

United States Department of Agriculture

Economic Research Service

Economic Information Bulletin Number 194

August 2018

Before Implementation of the Food Safety Modernization Act's Produce Rule: A Survey of U.S. Produce Growers

Gregory Astill, Travis Minor, Linda Calvin, and Suzanne Thornsbury





United States Department of Agriculture

Economic Research Service www.ers.usda.gov

Recommended citation format for this publication:

Astill, Gregory, Travis Minor, Linda Calvin, and Suzanne Thornsbury. *Before Implementation of the Food Safety Modernization Act's Produce Rule: A Survey of U.S. Produce Growers*, EIB-194, U.S. Department of Agriculture, Economic Research Service, August 2018.

Cover image: Getty images.

Use of commercial and trade names does not imply approval or constitute endorsement by USDA.

To ensure the quality of its research reports and satisfy governmentwide standards, ERS requires that all research reports with substantively new material be reviewed by qualified technical research peers. This technical peer review process, coordinated by ERS' Peer Review Coordinating Council, allows experts who possess the technical background, perspective, and expertise to provide an objective and meaningful assessment of the output's substantive content and clarity of communication during the publication's review.

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at How to File a Program Discrimination Complaint and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.



Economic Research Service

Economic Information Bulletin Number 194

August 2018

Before Implementation of the Food Safety Modernization Act's Produce Rule: A Survey of U.S. Produce Growers

Gregory Astill, Travis Minor, Linda Calvin, and Suzanne Thornsbury

Abstract

The 2011 Food Safety Modernization Act's (FSMA) Produce Rule (PR)—formally known as the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"—was the first onfarm food safety regulation for produce to be consumed in the United States. It set specific disease-preventive requirements for produce that is sold and consumed raw. Teaming with U.S. Department of Agriculture's (USDA) National Agricultural Statistics Service (NASS) to conduct a two-part survey in 2015 and 2016, USDA's Economic Research Service (ERS) asked U.S. produce growers about microbial food safety practices already in place before the PR's implementation. This report presents survey descriptive statistics covering various food safety practices and measured costs.

Keywords: food safety practices; microbial contamination; produce; produce growers; Food Safety Modernization Act (FSMA); Produce Rule (PR); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Produce Grower Food Safety Practices Surveys.

Acknowledgments

The authors thank Nathanial Warenski and Shareefah Williams, U.S. Department of Agriculture's National Agricultural Statistics Service, for their work developing and implementing the surveys, as well as the produce growers who participated in the survey. They also thank the following individuals for peer technical reviews: Linda Abbott, USDA, Office of the Chief Economist; Aaron Adalja, Cornell University; Samir Assar, U.S. Food and Drug Administration; Kathryn Boys, North Carolina State University; Elina Page, USDA, Economic Research Service; Leanne Skelton, USDA, Agricultural Marketing Service; and Nathanial Warenski, USDA, National Agricultural Statistics Service. Thanks also to Maria Williams and Cynthia A. Ray, USDA, ERS, for editorial and design services.

About the Authors

Gregory Astill, Travis Minor, Linda Calvin, and Suzanne Thornsbury are agricultural economists with USDA, Economic Research Service (ERS).

Contents

Summary	ίi
Introduction	1
ERS/NASS Produce Grower Food Safety Practices Surveys and Reporting Results by PR Coverage and Size Categories	3
Overview of Current Food Safety Landscape and Measured Costs	6
Food Safety Practices Identified in the Produce Rule	3
Personnel Qualifications and Training1	4
Health and Hygiene1	7
Water Application	8
Manure Products	3
Animal Contamination and Harvesting	6
Equipment, Tools, Buildings, and Sanitation	0
Conclusions	7
References	9
Appendix A – Survey Details	2
Appendix B – Food Safety Modernization Act's Produce Rule Coverage Details	2
Grower Coverage	2
Commodity Coverage	2
Appendix C – Detailed Data Tables6	7
Appendix D – Imputation Robustness Checks8	0



United States Department of Agriculture

A report summary from the Economic Research Service

August 2018



Before Implementation of the Food Safety Modernization Act's Produce Rule: A Survey of U.S. Produce Growers

Gregory Astill, Travis Minor, Linda Calvin, and Suzanne Thornsbury

What Is the Issue?

The Food Safety Modernization Act (FSMA) is the most significant change to U.S. food safety laws in over 70 years. Though enacted in 2011, it has yet to fully take effect. One piece of this legislation, commonly referred to as the "Produce Rule" (PR), was the first onfarm U.S. Food and Drug Administration (FDA) regulation for produce to be sold and consumed raw in the United States and set specific disease-preventive requirements governing a wide range of practices. These include personnel qualifications and training; health and hygiene; water application; manure products; animal contamination and harvesting; equipment, tools, buildings, and sanitation; and recordkeeping. Some PR requirements are already in effect for larger growers, and the last compliance deadline for smaller growers is January 2020. These deadlines do not include compliance dates for water requirements that have been unofficially proposed through 2024.

Before the rule was implemented, U.S. Department of Agriculture's (USDA) Economic Research Service (ERS) teamed with USDA's National Agricultural Statistics Service (NASS) to survey produce growers about their food safety practices. Based on these survey data, this report provides USDA's first update of national food safety practices since 1999 and since microbial contamination of produce became widely recognized and researched. The report reveals work yet to be done in training and implementation of food safety practices, as the PR implementation moves forward.

What Did the Study Find?

Growers' rates of adopting food safety practices vary by PR coverage and size category. At the time of the survey, many growers who would be covered by the PR already had some food safety practices in place. Of these, larger growers had adopted food safety practices at higher rates than smaller growers. Because growers with higher sales generally operated more produce acres, the share of acres on which food safety practices were in place far exceeded the share of growers who implemented food safety practices.

Small farms required more change to meet the PR standards than large farms. At the time of the survey, many farms that would be covered by the PR needed to make some changes to meet the standards. On average, smaller farms needed to make more changes than larger farms. Even growers who engaged in a particular food safety practice may not have performed it to the specifications of the PR. For example, some growers who tested water did not test as often as required by the PR or did not use a test standard that met PR requirements.

ERS is a primary source of economic research and analysis from the U.S. Department of Agriculture, providing timely information on economic and policy issues related to agriculture, food, the environment, and rural America.

Both growers who would not be covered and who would have a qualified exemption used some food safety practices. Some growers who would not be covered by the PR and would not be required to adopt new food safety practices had done so anyway. However, as a whole, this group was the least likely to have food safety practices in place. It was not uncommon for growers with a qualified exemption to the PR to have more food safety practices in place than growers of the same size who would be covered.

Larger growers spent more than smaller growers on the food safety practices measured in this report. Survey results provide a general idea of how much growers spent on some food safety practices already in place—which should not be interpreted as the cost to meet the standards of the PR or a complete measure of costs for food safety practices. Very large growers (taking in \$5 million or more in annual sales) covered by the PR spent about 16 times the amount on food safety practices as growers not covered by the PR.

Audited growers spent more than growers without audits on the food safety costs measured in this report. The costs for audited growers served as an imprecise proxy for expenses for growers who may already have had sufficient, or nearly sufficient, food safety practices to meet the standards of the PR. Audited growers spent on average about 2 to 10 times more on measured costs than growers without audits, depending on their PR and size coverage category. The lower costs for those without audits indicated a probable need to implement additional food safety practices to meet the PR's standards.

How Was the Study Conducted?

The Produce Grower Food Safety Practices Survey was conducted in two parts with the U.S. fruit and vegetable industry. NASS collected data for onfarm food safety practices using addendums to the 2015 Fruit Chemical Use Survey and the 2016 Vegetable Chemical Use Survey. The survey focused on grower activities related to food safety, including third-party audits (although not required by the PR); measured costs; personnel qualifications and training; water application; manure products; animal contamination and harvesting; equipment, tools, buildings, and sanitation.

Before Implementation of the Food Safety Modernization Act's Produce Rule: A Survey of U.S. Produce Growers

Introduction

Foodborne illness linked to contaminated produce is a public health concern. An estimated 48 million episodes of foodborne illness and 3,000 deaths occur per year in the United States (Scallan et al., 2011). The most common foodborne pathogens (those that make up 95 percent of illnesses attributed to all food) cause \$14 billion in annual losses for consumers in the United States (Hoffmann et al., 2012). The Centers for Disease Control and Prevention attributed 46 percent of foodborne illnesses with a known source in the period 1998-2008 to contaminated produce (Painter et al., 2013). Produce includes crops such as fruit, berries, vegetables, herbs, and tree nuts.

The science on food safety practices for produce and the impact on human health is still evolving. Concern about microbial food safety for produce dates to the mid-1990s, following several outbreaks involving both domestic and imported produce (Calvin, 2003). In response, the U.S. Food and Drug Administration (FDA) developed voluntary produce food safety guidelines, known as Good Agricultural Practices or GAPs, published in 1998 (FDA, 1998). After the 2006 foodborne-illness outbreak linked to California spinach, the industry began to put together best practices for food safety. The produce industry also developed and funded the Center for Produce Safety devoted to research issues facing produce growers. During this period, some in the produce industry began to advocate for Federal oversight of produce food safety (Stenzel, 2009). Subsequent outbreaks increased calls for regulation.

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. FSMA established a national approach to regulating food safety, shifting the policy focus from reaction to foodborne-illness outbreaks to risk-based preventive action. Part of the law directed the FDA to establish rules for science-based minimum standards for the safe production and harvesting of produce. FDA released the final rule entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," commonly known as the Produce Rule (PR), on November 27, 2015 (FDA, 2015a).

The PR was the first onfarm FDA regulation for produce, whether domestic or imported, destined for consumption in the United States and set specific food safety practice requirements to reduce the risk of microbial contamination. For example, the 1998 GAPs guidance document advised growers to use water quality "adequate" for the needs of the operation. The mandatory PR specifies exactly what quality is required for different types of water applications, how to measure quality, and how often to test the water. The PR requirements focus on the following aspects of food safety: personnel qualifications and training; health and hygiene; water application ("agricultural water"); manure products ("biological soil amendments of animal origin" (BSAAO)); animal contamination and harvesting ("domesticated and wild animals," "growing, harvesting, packing, and holding activities"); equipment, tools, buildings, and sanitation; recordkeeping; and special requirements for sprouts (not covered in this report) (table 1). The PR became effective on January 26, 2016, and

¹While the U.S. Department of Agriculture (USDA) regulates food safety for meat, poultry, and some egg products, the FDA regulates microbial food safety for produce.

compliance dates for all requirements other than those covering water application are scheduled as follows: January 2018 for growers with more than \$500,000 in annual produce sales, January 2019 for growers with over \$250,000 but no more than \$500,000 in sales, and January 2020 for growers with over \$25,000 but no more than \$250,000 in sales. Not all growers must comply with all the PR requirements, as we will discuss later. Readers should refer to the original sources for official language and interpretation of the rule (FDA, 2018; FDA, 2015a).

More fully understanding the economic effects of the PR on U.S. produce farms requires knowledge of food safety practices already in place before the rule becomes mandatory. National data for such an analysis are very limited. As part of the rulemaking process, FDA (2015b) carried out a benefit-cost analysis of the requirements that relied heavily on the "1999 Fruit and Vegetable Agricultural Practices" survey, conducted by the U.S. Department of Agriculture's (USDA) National Agricultural Statistics Service (NASS) (USDA, NASS, 2001). The survey, which provided a baseline of food safety practices, covered 30 commodities in 14 States and represented the best source of information on food safety activities on the farm at that time. However, the survey did not ask about costs of food safety practices, and the information is now very dated. The idea of food safety in produce was in its infancy in 1999, and since then, many growers have voluntarily adopted food safety practices.

In the absence of more recent national data, a number of researchers initiated independent surveys or case studies to provide information on this critical issue. Many studies focus on relatively small producers in one or a few States. Some studies investigate what onfarm food safety practices farms are using (Hultberg et al., 2012; Cohen et al., 2005; Rangarajan et al., 2002). Others look at both practices and costs (Adalja and Lichtenberg, 2018; Calvin et al. 2017; Lichtenberg and Tselepidakis Page, 2016; Marine et al., 2016; Sullins, 2014; Prenguber and Gilroy, 2013; Becot et al., 2012; Hardesty and Kusunose, 2009; Tootelian, 2008). The largest of this last group of studies covers 394 growers with a national scope and a focus on growers who belong to sustainable agriculture organizations, who tend to be smaller than average growers (Adalja and Lichtenberg, 2018).

Table 1

Key requirements of the Produce Rule (PR) examined in this report

Key requirement	Applies to	Further details
Personnel qualifications and training	Food safety person, workers who contact the produce, supervisors, and visitors	Table 2
Health and hygiene	Workers who contact the produce, supervisors, and visitors	Table 3
Water application	Water applied in production, harvest, and postharvest called "agricultural water" by FDA	Table 4
Manure products	Treated compost and untreated manure included under "biological soil amendments of animal origin (BSAAO)"	Table 5
Animal contamination and harvesting ¹	All harvestable produce covered by the PR	Table 6
Equipment, tools, buildings, and sanitation	Equipment and tools intended or likely to contact covered produce; instruments or controls that measure, regulate or record conditions; buildings used for covered activities	Table 7

¹Called "domesticated and wild animals" and "growing, harvesting, packing, and holding activities" by FDA.

Notes: This report does not contain analyses of practices for all PR requirements, like sprouts. A short discussion of Records is included in the box, "Recordkeeping."

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the U.S. Food and Drug Administration (FDA) website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to the original sources of this table for official language and interpretation of the rule.

To address the need for a larger sample of recent national data, the USDA Economic Research Service (ERS), in conjunction with NASS, carried out a new national survey of produce food safety practices and costs in 2015 and 2016. The project consisted of three separate surveys—two for grower food safety practices and one looking at postharvest operator food safety practices. This report provides the first summary of results from the two grower surveys. From a policy perspective, such information is critical to understanding the difference between what growers who will be covered by the PR have done in the past with respect to food safety and what they need to do.

ERS/NASS Produce Grower Food Safety Practices Surveys and Reporting Results by PR Coverage and Size Categories

ERS and NASS added a series of questions on food safety practices and costs to the existing NASS 2015 Fruit Chemical Use Survey (USDA, NASS 2016a) and 2016 Vegetable Chemical Use Survey (USDA, NASS 2017a). See Appendix A and the survey instrument for more detail. In both years, responses were collected in-person by NASS staff from October through the following January. Although each Chemical Use survey asks about chemicals only on the target fruit or only on the target vegetables in a specific year, growers were asked to consider all produce crops grown on their operation when they answered the food safety questions. We aggregate grower responses from both years into a single sample. Aggregating both years of data provides a measure of average practices over this 2-year period prior to the implementation of the PR. The combined sample consists of 4,618 growers and 1,262,604 acres of produce.

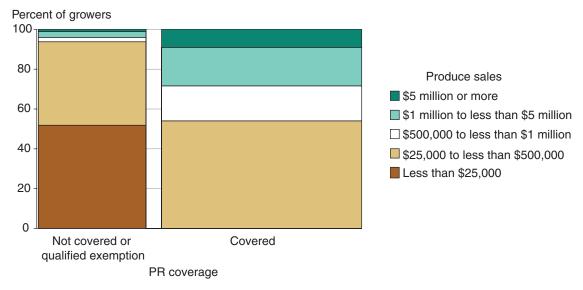
To analyze the survey results, we break down growers into PR coverage and size categories. In our analysis: very small farms had less than \$25,000 in produce sales, small farms had \$25,000 or more but less than \$500,000 in sales, midsize farms had \$500,000 or more but less than \$1 million in sales, large farms had \$1 million or more but less than \$5 million in sales, and very large growers had \$5 million or more in sales.²

When reporting results, we further categorize growers by PR coverage. The PR does not cover all produce growers and offers a qualified exemption to a specific group of growers. A covered grower must comply with the PR requirements on covered commodities. However, some or all of the grower's commodities may not be covered or may be eligible for an exemption. Growers who are not required to comply with the PR may still decide to adopt PR food safety practices for their own risk management needs or to meet the demands of their buyers. We sort growers from the survey into three categories: those covered by the PR, those not covered, and those eligible for a qualified exemption. Several simplifications are required to match survey responses to these three categories; see Appendix B for more details on PR coverage.

²In the PR, small growers are defined as having "\$25,000 or less" in produce sales (versus "less than \$25,000" in the survey results). The survey division of growers with produce sales are not identical to those used in FDA's Final Regulatory Impact Analysis (FDA, 2015b). Our division of growers with produce sales of \$500,000 or more is similar to the ERS farm size typology (Hoppe and MacDonald, 2016) although those groups are measured in terms of gross farm sales while, in this analysis, we use produce sales.

Figure 1 shows the breakdown of growers by size and by whether they would not be covered by the PR, eligible for a qualified exemption, or covered using our definitions. (For an explanation of mosaic plots like figure 1, see box, "How To Read the Mosaic Plots Used in This Report.") Figure 2 applies the same PR coverage and size breakdown to growing area (acreage). Growers with a 3-year average of less than \$25,000 in annual produce sales would not be covered by the PR (18.2 percent of all growers and 1.9 percent of total acres; appendix table B-2). Likewise, another 8.9 percent of growers (about 7.1 percent of acres) with a 3-year average of at least \$25,000 or more in annual produce sales would not be covered because they grew only commodities that were "rarely consumed raw" or because they processed with a kill-step. All of these growers are reported together as a single group of "not covered," but this group is diverse (see Appendix B). Growers eligible for a qualified exemption made up 8.1 percent of the sample (about 1.1 percent of acres). That left 64.8 percent of growers and 89.9 percent of acres covered by the PR. Although the FDA Final Regulatory Impact Analysis based on the 2012 Census of Agriculture found only 28.9 percent of growers covered by the PR, these growers accounted for 70 percent of produce acres (FDA, 2015b) (see Appendix A). The collection method used in our survey makes it well suited to describe the difference in food safety practices used by growers of different sizes and PR coverage groups prior to implementation of the PR. Our survey shows a smaller share of small growers covered by the PR than the share shown by the census of agriculture, but the share of growers covered by the PR in our survey accounts for a share of produce acres on par with that of the census of agriculture.

Figure 1
Size categories of produce growers by Produce Rule (PR) coverage for all growers, 2015/16



Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data from this figure in appendix table R-2

How To Read the Mosaic Plots Used in This Report

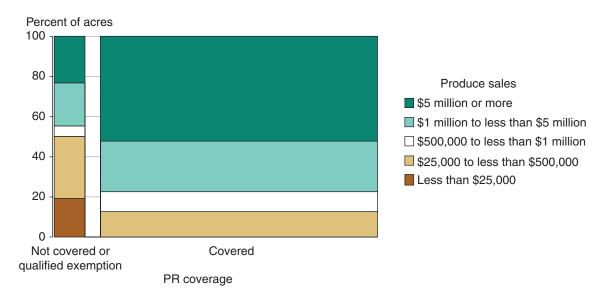
Interpretation of Mosaic Plots. Mosaic plots, such as that in figure 1, facilitate quick and intuitive comparisons of the relative sizes of cross-tabulation categories. It is easy to see from the height of the bottom column segment in the left column that about half of growers not covered by the Produce Rule (PR) or with a qualified exemption sold less than \$25,000 in produce annually. No growers covered by the PR, in the right column, sold less than \$25,000 in produce annually. Comparing the top three column segments in the left column to those in the right column, only a few growers not covered by the PR or with a qualified exemption sell \$500,000 or more in produce annually while about half of growers covered by the PR fall into one of these three groups. It is also easy to see from the column widths that within the sample there are more growers covered by the PR than not covered or with a qualified exemption. There is a cross-tabulation table associated with each mosaic plot that provides the exact numbers, and each cell in the table represents the share of growers (or acres) within the column. Determining the share of a group that spans more than one column or row requires some additional calculations.

Calculations from Data Tables. Calculating the share of the sample contained in more than one column segment requires adding up the areas of the column segments. For example, using figure 13 to calculate that 74.0 percent of growers who applied untreated, preharvest ground or surface water that contacts produce are covered, add up the widths of the columns for small, midsize, large, and very large growers. In the corresponding appendix table C-6, add up the four numbers in the bottom-most, "All growers" row for the small, midsize, large, and very large grower columns: 38.9 + 14.0 + 14.7 + 6.4 = 74.0 percent.

To better contextualize the covered growers who made up 74.0 percent of those who applied untreated, preharvest ground or surface water that contacts produce, consider that they accounted for 27.6 percent of all growers in the sample. To calculate this using the corresponding appendix table C-6, add up the same four numbers and multiply them by the number of growers in the subsample reported in the table "Note" divided by the number of growers in the sample: $(38.9 + 14.0 + 14.7 + 6.4) \times (1,725/4,618) = 27.6$ percent.

To determine the share of a group that spans more than one column and more than one row, the widths of the columns must be accounted for. To calculate that 33.0 percent of covered growers who applied untreated, preharvest ground, or surface water that contacted produce tested the water using an established numerical standard ("EPA drinking water" and "Other established numerical standard"), add up the areas of the bottom two column segments in each covered column (i.e., the small, midsize, large, and very large growers), and divide that sum by the share of growers in those columns. In the corresponding appendix table C-6, for each of the covered columns, multiply each number in the top two rows ("EPA drinking water" and "Other established numerical standard") by the share of growers in that column (the number in the "All growers" row) to calculate each area. Sum the areas and divide by the share of covered growers in the sample (the sum of numbers in the "All growers" row for covered columns): $((16.2 \times 38.9) + (10.7 \times 38.9) + (16.5 \times 14.0) + (16.9 \times 14.0) + (19.7 \times 14.7) + (21.3 \times 14.7) + (12.6 \times 6.4) + (37.8 \times 6.4)) / (38.9 + 14.0 + 14.7 + 6.4) = 33.0.$

Figure 2
Size categories of produce grower acreage by Produce Rule (PR) coverage for all growers, 2015/16



Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data from this figure in appendix table B-2.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—j ointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Overview of Current Food Safety Landscape and Measured Costs

Many growers had food safety plans and/or third-party food safety audits prior to the first PR compliance date (January 2018).³ Many retailers, foodservice providers, processors, and others—including the USDA school lunch program—require third-party food safety audits. Some growers belong to industry programs that require a food safety plan and third-party food safety audits.⁴ In addition, food safety plans and third-party audits are effective ways for many growers to manage their business risk.

A written food safety plan and the associated supporting documentation are required for all main-stream third-party food safety audits. Supporting documentation is a critical component of the PR (see box, "Recordkeeping"). An individual food safety plan involves growers examining their own operation and risk factors to develop a farm-specific plan of practices that will minimize the risk of introducing known or reasonably foreseeable food safety hazards. A third-party audit is a service provided by an outside (third-party) audit firm, in which an auditor goes to an operation to review its food safety plan and the records of the food safety practices it has carried out. The auditor also inspects the operation to determine whether the operation follows its food safety plan.

³In this report, we considered only third-party food safety audits concerned with microbial food safety. There are many other kinds of third-party audits that deal with other issues such as fair trade or sustainability.

⁴See Calvin (2013) for examples of voluntary and mandatory industry food safety programs that use written food safety plans and third-party food safety audits.

Recordkeeping

Records are a critical part of the Produce Rule (PR). Like private third-party food safety standards, growers covered by the PR are required to maintain records on almost all food safety activities performed, including when, where, for which product, and by whom all activities were performed. Records are to be created at the time the activity is carried out, by the person carrying out the activity, and dated and signed by that person. A supervisor or responsible party must review, date, and sign certain records within a reasonable time. In the survey, we did not ask specifically about time spent on recordkeeping. In this report, we include recordkeeping responsibilities in general food safety responsibilities for food safety staff, which we discuss in the chapter on Personnel Qualifications and Training.

Some important recordkeeping requirements for growers covered by the PR concern personnel training, including the date of training, topics covered, and the names of individuals trained. Records required to be kept on water include agricultural water system inspections, water tests, water treatment monitoring, and public water system certificates of compliance. Growers are required to keep records showing that purchased manure products were treated using a scientifically valid process; that purchased manure products were handled, transported, and stored to minimize contamination; and that measurements of the time, temperature, and turning for onfarm composted manure were completed. Finally, growers must maintain records of the dates and methods of cleaning and sanitizing equipment and tools used to harvest, pack, or hold covered produce.

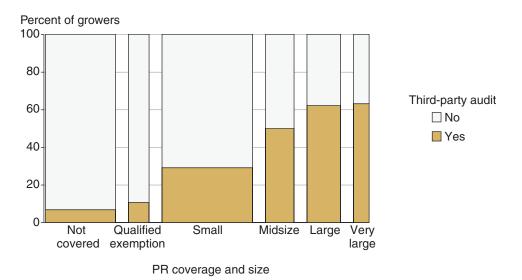
Growers who sell produce commodities that are not covered, who sell produce commodities that are exempt due to processing, or who are eligible for a qualified exemption are still required by the PR to keep some records. For example, growers who sell produce that receives commercial processing must keep records of disclosures and written assurances of final use. Growers who obtain a qualified exemption are required to keep records to demonstrate that they satisfy the criteria for a qualified exemption. Readers should refer to the original PR for official language and interpretation of the rule.

The PR does not require individual growers to develop their own food safety plans because the rule provides requirements expected to reduce the risk of microbial contamination. The PR also does not require third-party food safety audits, but FDA recommends them. Depending on the audit scheme and the qualifications of the auditor, audits have value as an indicator of PR readiness because they provide growers with the experience of following food safety and recordkeeping standards. We assume that produce growers who had not undergone third-party food safety audits may have been less familiar with principles and common procedures surrounding produce food safety and may find new practices and recordkeeping to be a substantial change in management of their operation.

Survey results show that 63.1 percent of very large growers had a third-party food safety audit compared to 29.2 percent of small growers, 10.7 percent of those with a qualified exemption, and 6.9 percent of not covered growers (fig. 3).⁵ These differences are statistically significant (between not covered growers, including those with a qualified exemption, and covered growers) for both growers and acreage.⁶ Growers with a third-party audit accounted for 30.1 percent of growers and 51.2 percent of acres in the sample.

Trends for written food safety plans were similar to those for audits, with a larger share of growers having a plan than an audit, within in each group (fig. 4). Of very large growers, over 88 percent reported having a written food safety plan, compared with 45.3 percent of small growers and 17.4 percent of growers not covered by the PR. Audits may not be the only driving force for having a written food safety plan. For example, a written plan without an audit may be a first step in a grower's efforts to identify and address food safety problems on the farm even if no buyer has yet asked for an audit. Having a written food safety plan may indicate a greater familiarity with food safety principles in general and a greater readiness to meet the PR recordkeeping requirements.

Figure 3
Use of third-party audits by grower Produce Rule (PR) coverage and size for all growers, 2015/16

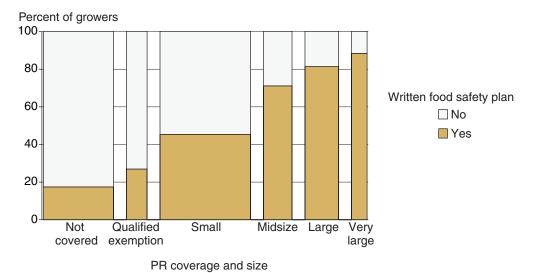


Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-1.

⁵Like most figures in this report, figure 3 has a corresponding detailed data table for both growers and acres in appendix table C-1.

⁶All data tables in Appendix C contain results from a test for statistical significance between not covered growers (including growers with a qualified exemption) and covered growers (small, midsize, large, and very large). Only for significance tests do we consider not covered and growers with a qualified exemption as a single group.

Figure 4
Use of written food safety plans by grower Produce Rule (PR) coverage and size for all growers, 2015/16



Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-1. Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly con-

ducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Measured Costs

The ERS/NASS Produce Grower Food Safety Practices Surveys asked growers a few questions about costs of some of the food safety practices that they were already doing. These average costs give a general idea of how much growers in different categories were spending on some food safety practices prior to the implementation of the PR, but they should not be interpreted as the cost of meeting the standards of the PR or a complete measure of food safety practices. The data are not fine enough to distinguish which costs were associated with practices that did not meet, that matched, or that exceeded the PR requirements. We include a subset of food safety costs that were relatively straightforward for growers to report: third-party audits (not required by the PR); water tests; water treatment; training materials for harvest workers; and cleaning and sanitizing equipment, tools, and bins. Not all growers answered every question, so calculations of average costs for a given practice include only growers who reported engaging in the associated food safety activity. The average costs presented here are too limited to draw hard conclusions. The data do convey relative magnitudes of some food safety costs.

Very large growers spent about 16 times the amount on the food safety practices measured in this report as growers not covered by the PR. Between each size category, from those with a qualified exemption to very large, total average measured food safety cost increased (from left to right, fig. 5). Very large growers spent about \$31,000 annually on five food safety practices, compared to \$8,000 for large growers, \$3,000 for midsize growers, \$2,000 for small growers, and \$1,000 for those with a

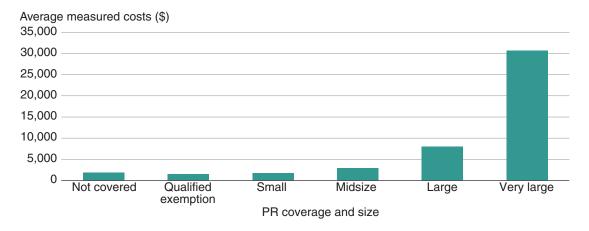
⁷In cases where growers reported an activity but no cost, it may be that some growers found estimating the cost to be too burdensome. However, it also may be possible that another entity paid the associated costs instead of the grower. For example, a grower may have received water test results free of charge from a nearby entity that was legally required to show it had not polluted surrounding waters. Thus, we include cost estimates of \$0 in reported averages for these growers. When we remove growers who reported \$0 cost, average costs are slightly higher, but trends are not substantively different.

qualified exemption. Growers not covered by the PR spent about \$2,000 annually on measured food safety practices.⁸

Water treatment cost was the largest cost for growers not covered by the PR, small growers, and very large growers (appendix table C-2). Despite a significant jump in water treatment costs for the largest farms, these costs were not statistically different for growers not covered by the PR (including those with a qualified exemption) and covered growers who reported treating water. Cleaning and sanitizing cost was greatest for growers with a qualified exemption, midsize growers, and large growers. Water testing was the smallest portion of costs for all PR coverage and size categories. The cost of audits was relatively high for all growers except the very large.

The cost per grower for those with audits is used as an imprecise proxy for expenses for growers who may already have had enough food safety practices to meet the PR standard. Growers without audits and growers who were not covered by the PR also had some food safety practices in place. Audited growers spent about 2 to 10 times more on food safety practices measured in this report than did growers without audits, depending on PR coverage and size category. The lower costs for covered growers without audits indicate a probable need to implement additional food safety practices to meet the standards of the PR. Costs for growers without audits rose steadily through the PR coverage and size categories (appendix table C-2), beginning with growers with a qualified exemption. Among covered growers with audits, costs increased with size. Notably, the costs per grower with a food safety audit were not statistically different between covered and not covered growers (including those with a qualified exemption), but costs differed between those groups when no food safety audit was reported.

Figure 5
Measured food safety practice average costs (\$) per grower by Produce Rule (PR) coverage and size for growers using food safety practices, 2015/16



Notes: The sample consists of 2,840 growers covering 868,348 acres. See detailed data for this figure in appendix tables C-2 and C-3.

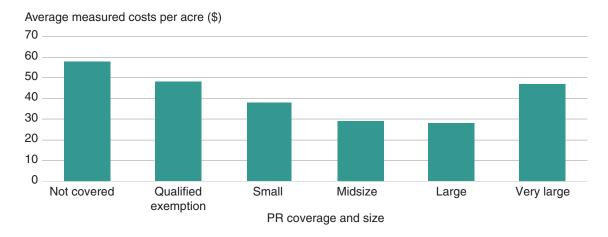
⁸Note that 67.2 percent of uncovered growers were very small, and 32.8 percent were small to very large (appendix table B-2).

⁹Audit fees do not include the cost of other activities that may be associated with an audit, such as the costs of preparing for an audit and the costs of implementing any changes afterward.

Costs per acre declined steadily (fig. 6) from not covered through large growers, but increased for very large growers. Not covered growers spent about \$60 per acre on the measured costs; those with a qualified exemption, \$50; small covered, \$40; midsize covered, \$30; large covered, \$30; and very large covered, \$50. Very large growers spent about as much as those with a qualified exemption on the measured food safety practices per acre. Costs per acre for very large growers may have exceeded those of other growers for a few reasons. Surveyed growers with packing houses spent more on food safety practices, and very large growers were more likely to have had a packing house. Audited growers surveyed spent more on food safety practices, and very large growers were more likely to have audits and were more likely to meet multiple audit standards—all of which may have increased costs. Also, very large growers reported more frequent cleaning and sanitizing compared to large, midsize, or small growers covered by the PR.

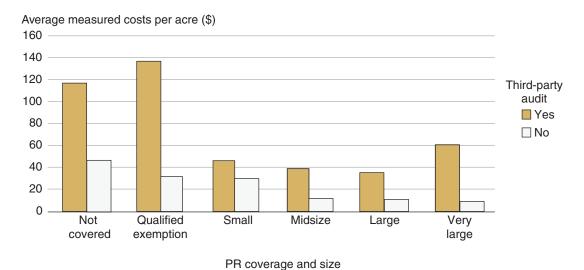
Per-acre costs of cleaning and sanitizing were greatest for all PR coverage and size groups except growers not covered by the PR (appendix table C-2). Cost of water testing per acre decreased from growers not covered by the PR to large growers. Per-acre cost of audits decreased across PR coverage and size except for very large growers. Cost per acre for growers with audits was 1.5 to 10 times greater than for those without audits, depending on PR and size coverage category (fig. 7). Cost per acre for growers without audits decreased across all PR coverage and size categories. However, of growers with audits, very large growers reported the third largest cost per acre, behind growers with a qualified exemption and growers not covered by the PR.

Figure 6
Measured food safety practice average costs per acre (\$) by Produce Rule (PR) coverage and size for growers using food safety practices, 2015/16



Notes: The sample consists of 2,840 growers covering 868,348 acres. See detailed data for this figure in appendix tables C-2 and C-3.

Figure 7
Measured food safety practice average costs (\$) per acre by audits and by Produce Rule (PR) coverage and size for growers using food safety practices, 2015/16



Notes: The sample consists of 2,840 growers covering 868,348 acres. See detailed data for this figure in appendix tables C-2 and C-3.

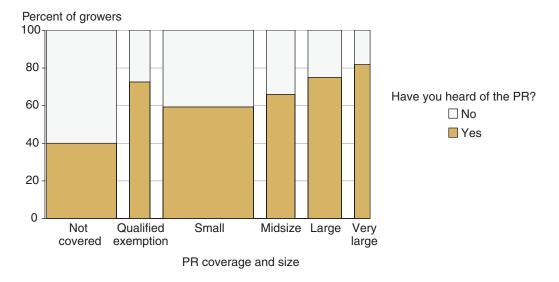
Food Safety Practices Identified in the Produce Rule

Although FSMA was signed into law in 2011, implementation of the PR did not begin until January 26, 2018, for growers with more than a 3-year average of \$500,000 in annual produce sales—with later deadlines for smaller growers set for 2019 and 2020. FDA, produce industry associations, cooperative extension, State Departments of Agriculture, consultants, and news organizations have launched major education efforts to disseminate information and opinions on the PR. By 2015 or 2016, 59.2 percent of all growers were aware of the PR, and that share accounted for 71.3 percent of U.S. produce acreage. Excluding growers with a qualified exemption, awareness of the PR increased (fig. 8) from 40.0 percent for uncovered growers to 81.8 percent for very large growers. However, awareness of the PR spiked among the 8.1 percent of growers with a qualified exemption—72.5 percent of these growers were aware of the PR. Growers close to the qualified exemption cutoff may have paid closer attention to development of the regulation.

This chapter discusses a simplified version of the adjustments needed to meet the PR requirements. Readers should consult the rule for exact requirements (FDA, 2018; FDA, 2015a). FDA requirements for specific food safety practices are compared with survey results to estimate how much growers in various size categories would need to change to meet the PR standard. Additional comparisons are made regarding growers who would not be covered by the PR or who would be eligible for a qualified exemption; growers who would be covered; and the acreage controlled by different grower categories.

Figure 8

Awareness of the Produce Rule (PR) by PR coverage and size for all growers, 2015/16



Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-1

Personnel Qualifications and Training

The PR requires that each operation have at least one food safety person, defined by FDA as a food safety supervisor or responsible party who has successfully completed food safety training, at least equivalent to that received under standardized curriculum recognized as adequate by FDA (table 2). All personnel must receive food safety training applicable to their roles. This training may include proper food safety procedures, proper sanitizing and cleaning of equipment and tools, or proper handwashing techniques. Visitors are required to be made aware of food safety policies and procedures.

Sample characteristics of personnel qualifications and training provide two main takeaways: about half of growers had a designated food safety person who often had to split his or her time among other activities; and about half of growers provided some level of food safety training for their harvest workers.

Food Safety Workers

A large percent of growers, 40.7 percent, already had a food safety person on staff; among covered growers, the percent increased with size (fig. 9). Of very large growers, 66.4 percent had a food safety person compared to 20.5 percent of growers who would not be covered by the PR. Growers with a qualified exemption were slightly more likely to have a food safety person than small growers (43.2 versus 38.9 percent). More than half of midsize and large growers had a food safety person (54.9 and 62.8 percent, respectively).

Table 2

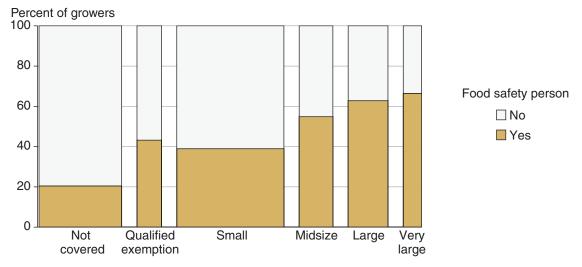
Produce Rule requirements for personnel qualifications and training

Applies to	Training requirements	Frequency
Food safety person ¹	Formal training at least equivalent to the food safety curriculum recognized by FDA	Once
Workers who contact produce or food-contact surfaces and their su- pervisors	Principles of food hygiene, food safety, personal hygiene, and worker illness How to identify contamination risks and measures to take to prevent contamination Requirements of the Produce Rule as they apply to their assigned responsibilities	At hiring and then at least annually after- wards
Visitors	Awareness of the food safety policies and procedures in place	As applicable

¹Defined by the U.S. Food and Drug Administration (FDA) as a food safety supervisor or responsible party who has successfully completed food safety training, at least equivalent to that received under standardized curriculum recognized as adequate by FDA.

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the FDA website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to the original sources of this table for official language and interpretation of the rule.

Figure 9
Have the one required food safety person by Produce Rule (PR) coverage and size for all growers, 2015/16



PR coverage and size

Notes: The sample consists of 4,618 growers covering 1,262,604 acres. We assume non-responses to mean "no food safety person." See detailed data for this figure in appendix table C-1.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

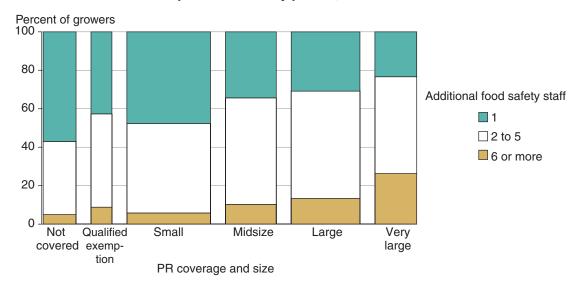
Covered growers who (at least at the time of the survey) had not yet identified a food safety person with approved training will need to do so. The food safety person, depending on the size of the operation, may spend a significant portion of his or her time managing food safety, monitoring how food safety policies are implemented, and maintaining food safety records. However, the person does not need to be full time and may wear multiple hats within the organization. ¹⁰ Food safety responsibilities may be more demanding at different times of the year, and skills useful in a food safety role may be transferable to other recordkeeping and management roles. Most food safety persons did not spend all of their time on food safety responsibilities (appendix table C-4). As expected, as PR coverage and size categories increased, so did the share of time the food safety person spent on food safety.

Many larger operations had more than one person working on food safety. Of all growers, 22.2 percent reported they had at least one additional person on the food safety staff—including harvest foremen and other staff to perform food safety and related recordkeeping tasks. This represents 54.5 percent of growers with one food safety person. Among growers with additional food safety staff, 39.1 percent had one additional staff member, 49.8 percent had two to five; and 11.1 percent had six or more. As size increased among covered growers, the share of growers with six or more additional staff increased; the share of growers with one additional staff decreased; and the share of growers with two to five staff increased and then decreased (fig. 10). Among growers with a qualified exemption, 48.5 percent had two to five additional food safety staff and 8.8 percent had six or more, compared to growers not covered by the PR of whom 38.0 percent had two to five additional food safety staff and 5.0 percent had six or more. Among very large growers, 23.4 percent had one additional food safety staff member; 50.4 percent, two to five; and 26.3 percent reported six or more.

¹⁰The activities and costs specific to food safety versus other responsibilities are often difficult to separate. While the salary and benefits of food safety staff may be substantial, they are not included in the estimated cost of food safety activities reported previously.

Figure 10

Number of additional food safety staff by Produce Rule (PR) coverage and size for growers with more than the one required food safety person, 2015/16



Notes: The sample consists of 1,024 growers covering 489,188 acres. We assume non-responses to mean "0 additional food safety staff." See detailed data for this figure in appendix table C-4.

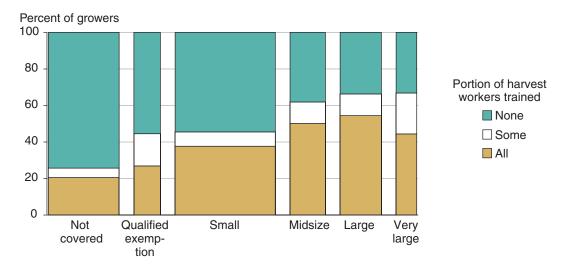
Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Harvest Workers

Harvest workers perform key roles in preventing the harvest of contaminated produce, and the survey had questions on their training. For all growers who reported having harvest workers, 46.8 percent, accounting for 56.4 percent of acres, trained at least some of their harvest workers in food safety practices. In general, among growers who used harvest labor, as farm size increased so did the share of growers who trained their harvest workers (fig. 11). Only 25.7 percent of growers not covered by the PR—compared to 66.8 percent of very large growers—trained at least some of their harvest workers. Large growers, at 54.4 percent, were the most likely to train all of their harvest workers. ¹¹

¹¹The true shares of harvest workers trained may be higher than reported here because contract harvesters who might be trained by the contract crew operator instead of the grower may not have been counted as having received training.

Figure 11
Training of harvest workers in food safety by size and Produce Rule (PR) coverage for growers reporting harvest workers, 2015/16



PR coverage and size

Notes: The sample consists of 3,799 growers covering 1,014,412 acres. We assume non-responses to mean "0 harvest workers trained." See detailed data for this figure in appendix table C-4.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Health and Hygiene

Health and hygiene requirements in the PR aim to prevent contamination of produce by sick individuals (table 3), including contamination of covered produce and food-contact surfaces by any person with a contagious health condition. Supervisors, workers who handle produce or food-contact surfaces, and visitors must take measures to prevent contamination of produce. Precautions include transferring a harvest worker who is showing symptoms of an illness to a job that does not require contact with produce or food-contact surfaces. The PR also stipulates training on handwashing and drying practices that must be used. Required training in health and hygiene is included in general training discussed in the previous chapter on Personnel Qualifications and Training.

Table 3

Produce Rule requirements regarding health and hygiene of personnel and visitors

Requirements	Applies to
Take measures to prevent contamination by ill or infected individuals	Workers who handle produce or food-contact surfaces, their supervisors, and visitors
Use hygienic handwashing and drying practices	Workers who handle produce or food-contact surfaces, their supervisors, and visitors

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the FDA website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to the original sources of this table for official language and interpretation of the rule.

Water Application

FDA identified water as an important, potential pathway of microbial contamination in produce and categorized the likelihood of contamination by water source and type of application (FDA, 2015c). Surface water is characterized as more likely to be contaminated by human pathogens than ground water because of the highly variable bacteria load in surface water, depending on temperature, precipitation, and exposure to animal waste. Although viewed as less likely to be contaminated than surface water, ground water can also be contaminated, with decreasing probability of contamination for deeper and newer wells. Public water systems are the least likely to be contaminated with microbial pathogens since they must meet the U.S. Environmental Protection Agency's (EPA) drinking water standards.

The type of water application system also affects the likelihood of contamination. Water applications can occur in preharvest (production), harvest, or postharvest activities. FDA cites research that suggests water applied directly to edible portions of the plant greatly increases contamination rates (FDA, 2015c). Direct-contact application methods during preharvest include water used in overhead irrigation, pesticide and fungicide application, and frost protection; the PR establishes testing rules for both ground and surface water applied this way. Other in-field application methods such as furrow, drip, and flood irrigation—where water does not contact edible portions of an above-ground crop—are treated differently. FDA does not impose any requirements for testing ground or surface water applied this way. During harvest and postharvest handling, water requirements are established for all practices where it is reasonably likely that contaminants can be transferred to the produce through direct contact. Examples include hydrating, washing, cooling, cleaning food-contact surfaces, hand washing, or making ice used to cool produce.

Table 4 shows the types of water and application methods that the PR regulates and the associated numerical testing requirements and frequencies. Untreated, preharvest ground or surface water that contacts produce must be tested to confirm the water meets acceptable standards. For harvest and postharvest activities, untreated ground water must be tested once a year to confirm that it meets the acceptable standard of no detectible *E. coli*, while the application of untreated surface water is prohibited. Water treated with a validated and monitored process to meet water test standards for intended use has no use restrictions, whether it was treated as a preventive measure or as a response to a failed test.

Sample characteristics of water application practices indicate three main takeaways. The majority of covered growers who must test preharvest, harvest, or postharvest water already did so. Half of these used an established numerical standard (EPA drinking water or other established numerical standard). The majority of preharvest ground water was tested frequently enough while the majority of surface water was not. The majority of harvest and postharvest ground water was tested frequently enough.

Table 4
Produce Rule (PR) microbial quality criteria and sampling requirements regarding untreated water used in preharvest, harvest, and postharvest activities¹

Water test requirements	Preharvest water that contacts produce ²	All water applied during harvest and postharvest ³
Test criteria	Geometric mean of ≤ 126 colony forming units (CFU) of generic <i>E. coli</i> per100 mL ⁴	No detectable <i>E. coli</i> per 100 mL
	Statistical threshold value of ≤ 410 CFU generic <i>E. coli</i> per100mL ⁴	
Untreated ground water sampling	4 sample initial survey ⁵	4 sample initial survey ⁵
	1 sample per year if no positive test results	1 sample per year if no positive test results
Untreated surface water sampling	20 sample initial survey ⁵	Use of untreated surface water is prohibited
	5 samples per year if no positive test results	

¹Originally scheduled for 2 years after all other requirement compliance dates, the FDA (2017c) proposed to postpone water requirement compliance dates an additional 2 years. Additionally, the FDA (2017d) announced that in response to feedback on the complexity of the water requirements, they are considering how the water standards might be simplified. Neither the water requirement dates nor simplified standards had been announced by the time of publication.

²In the PR, the U.S. Food and Drug Administration (FDA) regulates "water that is intended to, or is likely to, contact the harvestable portion of covered produce," which the agency terms "agricultural water." Examples of application methods that could directly contact the edible portion of produce include overhead irrigation, pesticide or fungicide application, and frost protection. Additionally, water used for irrigation that does not contact produce is not "agricultural water used for certain intended uses" according to the PR. FDA does not impose any requirements for testing ground or surface water used this way.

³Water uses "in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact" such as washing hands, produce, food contact surfaces, or making ice used to cool produce is also called "agricultural water."

⁴The geometric mean measures the average quality of the water samples and the statistical threshold value measures the variance of the quality of the water samples. The final PR stipulated water testing using Method 1603 (which reports results in CFU), but in September 2017, FDA announced that it had determined equivalency for other testing methods (FDA, 2017b), some of which report results in Most Probable Number (MPN).

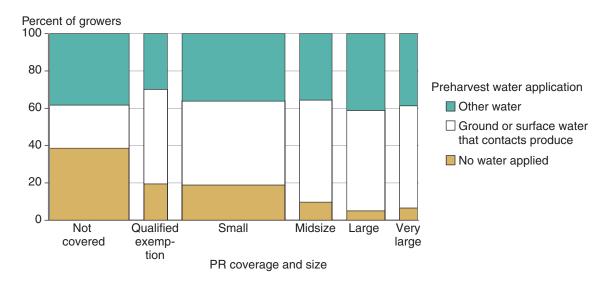
⁵Growers who must test water must also do an initial water survey over a period of 2 to 4 years, which is to be updated using annual sampling.

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the FDA website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to the original sources of this table for official language and interpretation of the rule.

Preharvest Water

Within the sample, 20.8 percent of growers applied no preharvest water in the field (i.e., they relied on rain water); 42.3 percent applied preharvest ground or surface water that contacts produce; and 36.9 percent applied preharvest water from any source that did not contact produce or public or other water that contacts produce (fig. 12). Larger growers, more often than smaller growers, applied preharvest water that contacts produce while smaller growers, more often than larger growers, applied no preharvest water. The difference between the share of covered and not covered growers (including those with a qualified exemption) who applied no preharvest water is significant at the 1-percent level for both grower groups. The same is true for those who applied preharvest ground or surface water that contacted the crops. The difference between shares of not covered and covered growers who applied another type of preharvest water that did not directly contact crops is not statistically significant at the 10-percent level.

Figure 12
Application of preharvest water by Produce Rule (PR) coverage and size for all growers, 2015/16



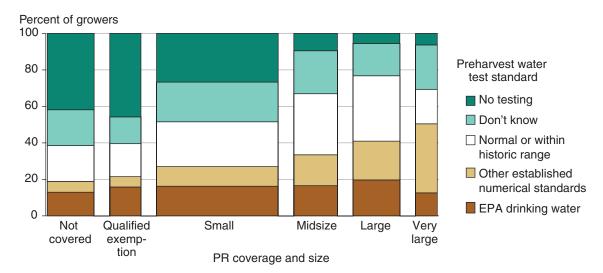
Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-5. Other water includes any preharvest water that does not contact produce or public or other water that contacts produce.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Growers who applied untreated, preharvest ground or surface water that contacts produce must test their water, and 74.0 percent of these growers were covered by the PR (fig. 13). Covered growers who must test their preharvest water represented 27.6 percent of all growers and 38.9 percent of all acres. Among these growers, 33.0 percent tested preharvest water using an established numerical standard (EPA drinking water standard or other established numerical standard). (See box, "How To Read the Mosaic Plots Used in This Report," calculations from data tables, on how to calculate the aforementioned percentages and others like them.) As grower size increased, so too did the share of growers using established numerical standards; very large growers were almost three times as likely as growers not covered by the PR to do so.

Among covered growers who would be required to test their preharvest water, 66.1 percent were already testing their water in 2015 and 2016 (excluding those who responded that someone else tested); however, most were not testing as frequently as required (fig. 14). Of growers who would be required to test ground water once a year, 70.8 percent reported testing at least this frequently. For surface water where five samples per year would be required, only 15.0 percent of growers reported that they were already meeting this more significant requirement, with another 40.9 percent testing between one and four times a year.

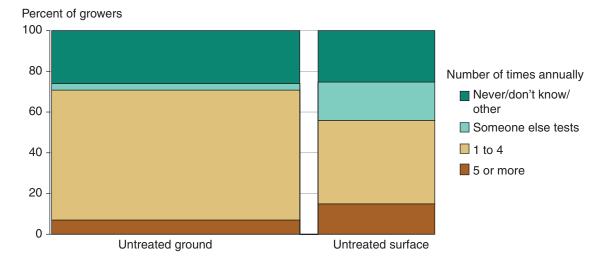
Figure 13
Water test standard by Produce Rule (PR) coverage and size for growers
who applied untreated, preharvest ground, or surface water that contacts produce, 2015/16



Notes: The sample consists of 1,725 growers covering 515,105 acres. See detailed data for this figure in appendix table C-6. Other standards include U.S. Environmental Protection Agency (EPA) recreational water standard, Leafy Greens Marketing Agreement (LGMA), maximum of 1,000 *E. coli* CFU/ml, maximum of 500 *E. coli* CFU/ml, reclaimed water standard, or other standards.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Figure 14
Water testing frequency by water source for growers covered by the Produce Rule (PR) who applied untreated, preharvest ground, or surface water that contacts produce, 2015/16



Preharvest water source

Notes: The sample consists of 1,278 growers covering 491,638 acres. See detailed data for this figure in appendix table C-7. Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys, 2015 and 2016.

Of growers who applied surface water, 18.9 percent relied on someone else to test their water, versus only 3.2 percent of growers who applied ground water. It may be possible that some growers relied on water tests from irrigation districts. Of covered respondents who applied untreated ground water, 26.0 percent reported no current testing regime, versus 25.3 percent of growers who applied untreated surface water that contacted produce. These growers would incur costs to meet the standard. While not required under the PR, 64.0 percent of covered growers tested the preharvest water they applied that did not contact produce.¹²

The water standard the PR requires for untreated, preharvest ground or surface water that contacts produce involves a maximum mean of the water quality tests and a limit on the variability of the tests. ¹³ Among growers covered by the PR who applied ground or surface water that contacts produce, 17.4 percent used the EPA *drinking* water standard, which exceeded what was required by the PR (appendix table C-8). The 17.6 percent using other established numerical standards were likely well positioned to adjust their tests to meet PR water requirements. ¹⁴ The 49.7 percent who reported using a standard of "normal or within historic range" or "don't know," as well as the 15.3 percent with no testing, would need to adopt an established numerical standard.

The PR allows growers to treat their water either to correct a problem identified through testing or to preclude potential problems. If growers use a treatment that is validated and monitored, they do not need to test their water. Growers commonly used ultraviolet light, filtration, or chemical treatments. A large majority (86.7 percent) of growers subject to testing for preharvest water that contacts produce used no treatment for their water or did not know, while only 13.3 percent reported treating their water (appendix table C-8).

Harvest and Postharvest Water

About one quarter (24.6 percent) of growers using harvest and postharvest water treated it (appendix table C-8). Among growers who treated harvest and postharvest water, 68.9 percent used ground water; 10.5 percent used surface water; and 19.3 percent used public water, which does not require testing or treatment. FDA does not allow growers to use more risky surface water for harvest and postharvest activities without treatment, but only 5.8 percent of growers who did not treat fell into this category. The majority of growers who did not treat harvest and postharvest water (74.4 percent) used untreated ground water and would have to test once each year. Of all growers who used untreated ground water, 15.7 percent tested two or more times annually and 48.7 percent tested once annually (fig. 15). Very large growers were about 10 times as likely as growers not covered by the PR to test 2 or more times annually.

¹²Growers covered by the PR who applied preharvest water that did not contact produce would not be required to test (36.9 percent of all growers using preharvest water used only this type), but some still tested their water. Of these covered growers not required to test, 5.2 percent had five or more tests per year compared to the 9.6 percent for the covered growers required to test the untreated, preharvest ground or surface water that contacts produce; 56.0 percent of the covered growers not required to test did so one to four times a year, which approaches the 56.5 percent for those covered and required to test. Of the covered growers not required to test, 11.0 percent reported that someone else tested their water; of those covered and required to test, this share was 8.2 percent. Also, of covered growers not required to test, 27.8 percent did not test, did not know if their water was tested, or had some other response; this share approximates the 25.7 percent of those covered and required to test.

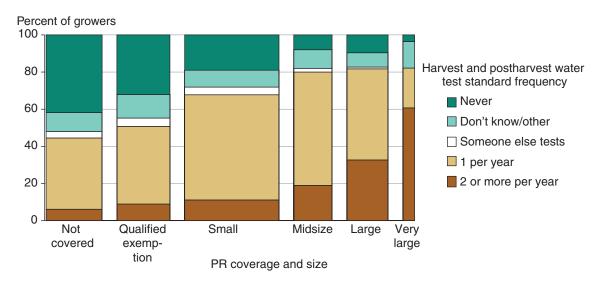
¹³A maximum geometric mean of 126 colony forming units (CFU) generic *E. coli* per 100 ml of water and a maximum statistical threshold value of 410 CFU generic *E. coli* per 100 ml of water.

¹⁴Other established numerical standards asked about in the survey included the EPA recreational water standard, the Leafy Greens Marketing Agreement (LGMA) standard, a maximum of 1,000 *E. coli* CFU/ml, a maximum of 500 *E. coli* CFU/ml, the reclaimed water standard, or another standard.

¹⁵Among growers who treated preharvest water that contacts produce, 54.4 percent used chemical treatment, 34.4 percent used filtration, and 11.2 percent used ultraviolet light.

Figure 15

Annual number of water tests by Produce Rule (PR) coverage and size for growers who applied untreated harvest and postharvest ground water, 2015/16



Notes: The sample consists of 754 growers covering 173,881 acres. See detailed data for this figure in appendix table C-6. Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Manure Products

The PR set requirements for the use of all biological soil amendments of animal origin (BSAAO), including but not limited to compost and manure. The type of manure product allowed by the PR depends on its application method, which influences the risk of contamination (table 5). Any kind of manure product that does not contact produce during application can be used, including untreated manure products such as raw manure or aged manure. If a manure product is applied in a way that minimizes contact with produce during and after application, it must be treated with a scientifically validated process, such as the EPA time and temperature requirements, and must be tested for fecal coliforms and *Salmonella* to ensure the microbial standard is met. In situations where growers cannot minimize the potential for contact during manure application, as in the case of root vegetables, the PR allows only the application of manure products that have been treated with a scientifically validated process designed to eliminate *Listeria monocytogenes*, *Salmonella* species, and *E. coli* O157:H7. This type of treated manure product has no use restrictions. Our survey focused on only compost and manure, referred to as "manure products" in this report.

Table 5
Produce Rule requirements regarding the use of manure products (biological soil amendments of animal origin (BSAAO))

Manure product (BSAAO)	Microbial standards for testing	Application requirement	Recommended harvest interval
Compost treated with a method scientifically validated to meet micro- bial standards ¹	Listeria monocytogenes, Salmonella species, and E. coli O157:H7 ²	Direct contact allowed during and after application.	None specified
	Salmonella species and fecal coliforms ³	Minimized contact with produce during and after application.	None specified
Untreated manure ⁴	No standard	No contact with produce during application and minimized potential for future contact	90 days for produce not in contact with soil; 120 days for produce in contact with soil

¹The U.S. Food and Drug Administration (FDA) uses the term "treated BSAAO," which includes animal manure products that have undergone controlled physical, chemical, or biological processes, or combinations thereof, that are validated to meet the FDA-set microbial standards.

³No detection of *Salmonella* species is allowed using a method that can detect three MPN *Salmonella* species per 4 grams (or milliliter) of total solids, and there must be less than 1,000 MPN fecal coliforms per gram (or milliliter) of total solids. Compost that meets the EPA's time and temperature requirements for Processes to Further Reduce Pathogens (PFRP) meets this microbial standard—specifically (1) "static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing and (2) turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing."

⁴The U.S. Environmental Protection Agency (EPA) uses the term "untreated BSAAO," which includes untreated, raw, and aged manure and compost teas that have not undergone a process scientifically validated to meet FDA-specified microbial standards.

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the FDA website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to the original sources of this table for official language and interpretation of the rule.

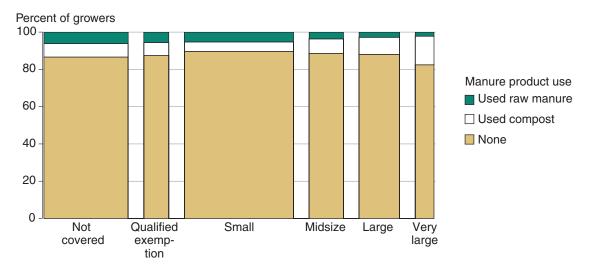
A set interval between the application of untreated manure and harvest is not required by the PR. The length of the interval was a point of significant controversy during the PR comment period. FDA has expressed plans to revisit and potentially re-propose new standards for the use of untreated BSAAOs after completing a risk assessment. However, FDA explicitly recommended that growers using untreated manure extend the days-to-harvest interval as long as possible, and does not currently object to following the National Organic Program standard on harvest intervals, which is 90 days for produce not in contact with the soil and 120 days for produce in contact with the soil.

²No detection is allowed for *Listeria monocytogenes* using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter) analytical portion, for *Salmonella* species using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter) of total solids and for *E. coli* O157:H7 using a method that can detect 0.3 MPN per 1 gram (or milliliter) analytical portion.

Sample characteristics of manure product use indicate three key takeaways: most growers did not use manure products; those that did usually had documentation regarding the treatment; and the majority of manure product users were not organically certified. Of the survey growers, 87.9 percent did not use manure products in 2015 and 2016 (fig. 16), while 12.1 percent of growers (with 16.7 percent of acres) used compost or untreated manure in their fields. Among these growers, 7.2 percent used compost only, and 4.9 percent used untreated manure (but may also have used compost). Generally, larger growers were more likely to use compost, and smaller growers were more likely to use untreated manure. There is a statistically significant difference between the share of growers not covered by the PR (including those with a qualified exemption) and covered growers with respect to the use of untreated manure, with uncovered growers using more.

Figure 16

Manure product use by Produce Rule (PR) coverage and size for all growers, 2015/16



PR coverage and size

Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-9. Growers using untreated manure may also use compost. Untreated manure includes both raw and aged manure. Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Across all growers who used manure products, 61.7 percent would be covered under the PR, and they represented 96.0 percent of acres in this group (appendix table C-9). Among covered growers who used manure products, 36.7 percent used untreated manure and would need to follow application rules, but our data do not reveal how many users of untreated manure would need to adjust to meet the PR. For growers using compost and covered under the PR, 74.3 percent reported that their compost met EPA time and temperature requirements, and they accounted for 91.2 percent of acres in this group (appendix table C-10). The 27.7 percent of growers with compost that met EPA requirements who did not have full documentation would need to obtain that documentation. Of covered growers using compost, 25.7 percent used compost that did not meet EPA time and temperature

¹⁶We consider all growers who used commercially treated manure products to have used compost that meets EPA requirements.

¹⁷The survey asked about the following types of documentation: time/temperature measurements, microbial testing results, Certificate of Conformance, Certificate of Analysis, or other. We consider compost coming from a source approved by an organic certifying agent to be equivalent to having documentation that the product met standards for pathogen die-off.

requirements and would need to transition to compost that does (15.6 percent lacked complete documentation; 10.1 percent had complete documentation but did not use compost that met EPA requirements—this share included those that did not know if purchased compost met EPA requirements). Of covered growers using compost, 68.3 percent already had documentation that the compost met EPA standards and would not need to make any changes.

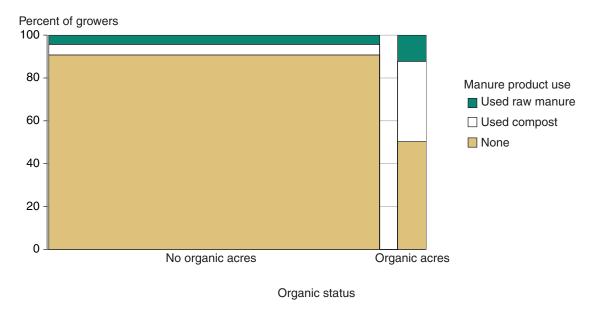
Manure products are especially important to organic growers who do not use synthetic fertilizers, but other growers also use manure products. Among all growers, 7.1 percent reported at least some organic acres while 92.9 percent reported only conventional acres (fig. 17). Among growers with organic acres, 49.7 percent used manure products, including 12.2 percent of growers with organic acres who used untreated manure. Among growers with no organic acres, 9.2 percent used manure products, including 4.3 percent of growers with no organic acres who used untreated manure. Among growers using manure products, organic growers used compost at a higher rate than conventional growers. Because growers with organic acreage were such a small share of all growers, 49.3 percent of acres with untreated manure were conventional, and 35.9 percent of acres with compost were conventional. This finding may in part result from the fact that some growers used organic practices but without organic certification so they were counted in the conventional category.

Animal Contamination and Harvesting

The majority of produce crops are grown outdoors in fields that are habitat for wild animals or near such habitat. Some produce crops may be near land used for animal agriculture. The main source of microbial contamination on produce crops from wild and domesticated animals is fecal matter. Where there is reasonable probability that animals may contaminate produce, the PR requires growers to assess the relevant areas for evidence of potential contamination as needed during the growing season. The "preharvest assessment" requires (among other measures) (1) a visual verification that produce to be harvested has not been contaminated by animal feces and (2) actions to identify and avoid harvesting contaminated produce (table 6). Unlike for some third-party audits, the PR does not require growers to establish harvest buffer zones of a specific size surrounding animal fecal contamination. There was concern that early versions of the PR might be interpreted to condone removing animal habitat near fields or to require the exclusion of wild animals from fields. The final version of the PR clarifies that it does not encourage or require either.

Figure 17

Manure product use by organic status for all growers, 2015/16



Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-11

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table 6
Produce Rule requirements concerning the presence of domesticated and wild animals

Requirements	Recommended
Visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used	Establish waiting periods between grazing and harvest appropriate to farm's commodities and practices
If significant evidence of potential contamination by animals is found, take measures reasonably neces- sary	Do not exclude wild animals from outdoor growing areas, do not destroy animal habitat, and do not clear borders around growing areas
Identify and do not harvest covered produce that is visibly contaminated with animal excreta	

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the U.S. Food and Drug Administration's website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to this table's original sources for official language and interpretation of the rule.

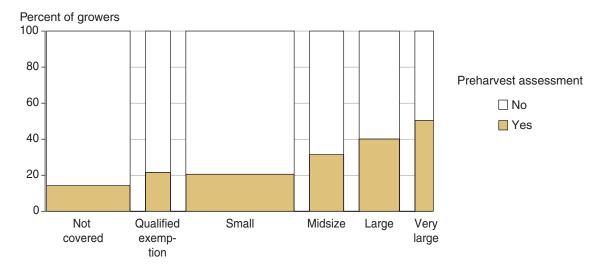
Sample characteristics of animal contamination and harvesting practices indicate three main takeaways: most growers did not perform a preharvest assessment; however, most growers did monitor for animal intrusion, and a majority of growers also used some type of intrusion prevention. At the time of the survey, 24.4 percent of all growers already performed a preharvest assessment within 3 days of harvest to identify potential microbial contamination. Among covered growers, 29.0 percent reported they already performed a preharvest assessment to identify potential microbial contamination, corresponding to 43.6 percent of covered acres. This left 71.0 percent of covered growers in the sample who would need to implement a preharvest assessment. Larger covered growers were more likely to report performing a preharvest assessment—50.8 percent of very large growers compared to 40.0 percent of large, 31.6 percent of midsize, and 20.6 percent of small

growers (fig. 18). A slightly higher share of growers with a qualified exemption (22.2 percent) than small growers reported performing preharvest assessments, but of all groups, the smallest share who reported performing preharvest assessments were the growers not covered by the PR—14.4 percent.

General monitoring (i.e., visual examination) of animal intrusion informs growers of likely sources and the extent of possible animal contamination. General monitoring is much more common than preharvest assessments. At the time of the survey, 69.9 percent of all growers monitored their fields. Of covered growers, 72.2 percent monitored their fields for animal intrusion, corresponding to 73.1 percent of covered acres. Larger growers were more likely than smaller growers to report monitoring for animal intrusion—81.6 percent of large growers and 81.4 percent of very large growers reported monitoring, followed by 78.1 percent of midsize growers and 65.4 percent of small growers (fig. 19). Growers with a qualified exemption reported close to the same amount of monitoring as midsize growers (77.8 percent). Not covered growers reported the lowest incidence of monitoring—62.0 percent. The difference between growers not covered by the PR (including those with a qualified exemption) and covered growers is statistically significant for intrusion monitoring, with covered growers monitoring more often.

Figure 18

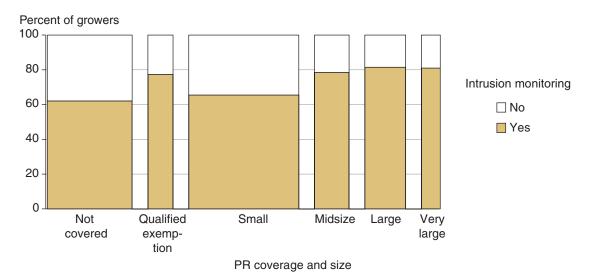
Preharvest assessment by Produce Rule (PR) coverage and size for all growers, 2015/16



Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-12

Figure 19

Animal intrusion monitoring by Produce Rule (PR) coverage and size for all growers, 2015/16



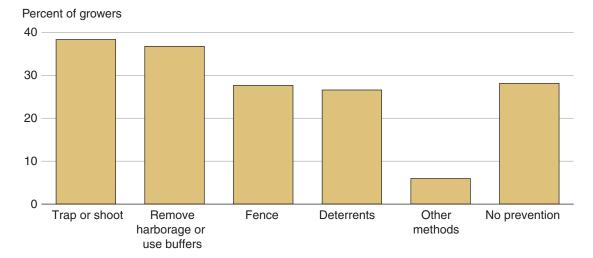
Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-12.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Although FDA notes that it does not encourage or require the use of any methods that would destroy wild animal habitat or prevent wild animals from entering fields in the name of food safety, growers may consider methods that reduce wild animal intrusion to be useful in preventing product loss. Use of animal intrusion prevention methods increases with size category for covered growers up to large growers (appendix table C-12). Of all growers in the sample, 71.9 percent used at least one method of intrusion prevention (in descending order of preference): trapping or shooting; removing harborage and using buffers or clearing buffer zones, installing fencing, using deterrents, and using other methods (fig. 20).¹⁸

¹⁸Deterrents include noise makers, gunfire, Mylar strips, fake owls or coyotes, and repellants.

Figure 20 **Animal intrusion prevention methods used for all growers, 2015/16¹**



Intrusion prevention method

¹Growers could report multiple intrusion prevention methods.

Notes: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data for this figure in appendix table C-13. Deterrents include noise makers, gunfire, Mylar strips, fake owls or coyotes, and repellants. Fence refers to fencing erected around fields or around standing surface water. Harborage includes excess brush, old equipment, and cull piles; buffer zones around a field are intended to increase the ability to detect animal intrusion. Other methods reported by growers include closely monitoring crops, baiting rodents, encouraging natural predators, using dogs, using bird netting, fencing young fruit trees, and using services of State and national wildlife management agencies.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Equipment, Tools, Buildings, and Sanitation

The Produce Rule requires that growers inspect, maintain, clean, and sanitize ("when necessary and appropriate") the equipment and tools that come into contact with covered produce (table 7). Cleaning involves washing and removing debris. Sanitizing reduces or kills microorganisms of public-health concern. Installation, storage, and maintenance of equipment and tools should facilitate cleaning and prevent contamination. The PR requires that instruments used to measure, regulate, or record important food safety indicators (like cooler thermometers, pH meters, etc.) be accurate, precise, adequately maintained, and adequate in number. Regarding buildings, the PR requires the following: providing adequate drainage; preventing contamination of food-contact surfaces; excluding domestic animals from fully enclosed buildings or separating them from areas where covered activities take place; excluding pests from fully enclosed buildings; and preventing pests from becoming established in partially enclosed buildings. The PR specifies that farms must provide adequate and readily accessible toilets and handwashing facilities and provide for sanitary disposal of waste and toilet paper. Toilet facilities must be sufficiently serviced and cleaned.

Sample characteristics of equipment, tools, buildings, and sanitation practices indicate three main takeaways: regardless of packing method, a majority of growers performed cleaning activities daily; growers performed cleaning more frequently than sanitizing; and the majority of growers provided toilets and handwashing sinks for their harvest workers.

Table 7
Produce Rule requirements regarding equipment, tools, buildings, and sanitation

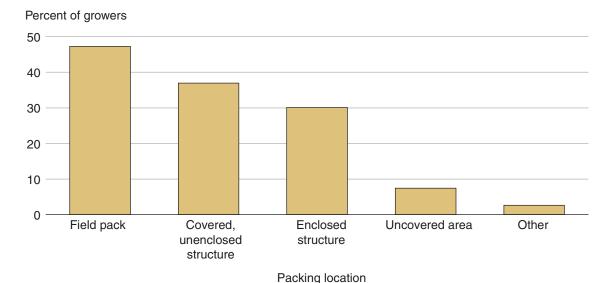
Applies to	Requirements		
Equipment and tools			
Intended to, or likely to, contact covered	Install and maintain in ways that facilitate cleaning		
produce	Store and maintain to protect covered produce from being contaminated with hazards and pests		
	Inspect, maintain, clean, and when necessary and appropriate, sanitize all food-contact surfaces		
	Maintain and clean all non-food-contact surfaces		
Instruments and controls			
Measure, regulate, or record conditions	Ensure they are accurate and precise, adequately maintained, and adequate in number		
Buildings			
Fully or partially enclosed and used for covered activities	Ensure adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building		
	Prevent contamination of covered produce and food-contact surfaces in buildings		
	For fully enclosed buildings, exclude domestic animals or separate domestic animals by location, time, or partition from areas in buildings where covered activities are conducted. Guard or guide dogs may be allowed in some areas when contamination is unlikely.		
	Exclude pests from fully enclosed buildings and prevent pests from becoming established in partially enclosed buildings.		
Toilet and handwashing facilities			
	Provide adequate, readily accessible toilet and handwashing facilities, which include preventing contamination with human waste, performing sufficient servicing and cleaning, and providing sanitary disposal of waste and toilet paper.		
	Maintain waste systems and dispose of waste through adequate means.		

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" fact sheet published on the U.S. Food and Drug Administration's website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to this table's original sources for official language and interpretation of the rule.

Cleaning and Sanitizing

Many types of equipment, tools, or bins were used in harvesting, field packing, or packing house, and they may have had different cleaning and sanitation schedules. Among all growers, 26.2 percent reported packing their produce in the field, in a structure, or both (fig. 21). Among this group, the most common location to pack produce was in the field, which was used by 47.3 percent of growers. Packing in a covered, unenclosed structure was the second most common location (36.9 percent), followed by packing in an enclosed structure (30.1 percent), an uncovered area (7.4 percent), or other location (2.6 percent).

Figure 21 Packing or packaging location for grower who packed or packaged, 2015/16¹



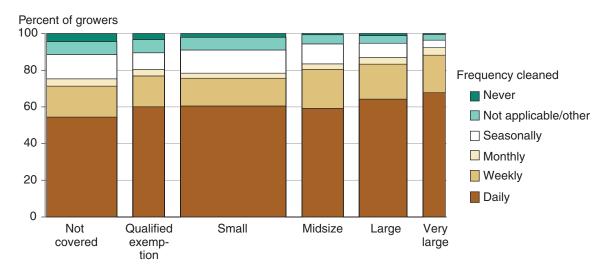
¹Growers could report packing both in the field and one other location.

Notes: The sample consists of 1,210 growers covering 421,220 acres. We do not include 31 growers who report packing but do not distinguish field packing or packing house or who do not report the structure of their packing house.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

We expect that growers would likely have cleaned or sanitized the highest risk areas most frequently. Thus, for each grower who reported cleaning a variety of equipment, tools, or bins with different schedules, we record only the most frequent schedule that grower reported using. For example, if a grower reported cleaning three different items on three different schedules—daily, weekly, and monthly—then that grower is recorded as cleaning daily. Almost all growers cleaned on some level. Most commonly, cleaning was carried out daily (60.0 percent of growers), followed by weekly (17.4 percent), seasonally (10.9 percent), and monthly (3.4 percent) (fig. 22). Cleaning was not applicable, was performed on some other schedule, or was never performed in 8.4 percent of cases. Practically all very large growers and 95.6 percent of not covered growers performed some level of cleaning on their equipment, tools, and bins. Larger growers reported slightly higher frequencies of cleaning, but differences between growers not covered by the PR (including those with a qualified exemption) and covered growers are statistically significant only for daily cleaning and never cleaning, at the 1-percent level.

Figure 22 Cleaning schedule by Produce Rule (PR) coverage and size for growers who use harvest, field pack, or packing house equipment, tools, or bins, 2015/16



PR coverage and size

Notes: The sample consists of 3,380 growers who use harvest or field packing tools, harvest or field packing machinery, packing house tools, postharvest machinery and work surfaces, harvest bins, and transportation bins. The figure shows respondents' most frequently reported cleaning of multiple items. See detailed data for this figure in appendix table C-14.

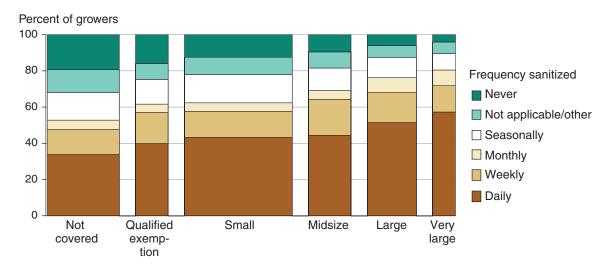
Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

All grower groups sanitized less frequently than they cleaned (fig. 23). Among growers who used equipment, tools, or bins in harvesting, field packing, or packing in a building, sanitation was most commonly carried out daily (43.1 percent), followed by weekly (15.6 percent), seasonally (13.8 percent), and monthly (5.6 percent). Differences in sanitation frequency among not covered growers, those with a qualified exemption, and very large growers are more pronounced than the differences in cleaning frequency. Of very large growers, 4.1 percent never sanitized compared to 19.4 percent of not covered growers and 16.0 percent of exempt growers. The difference in daily sanitizing and never sanitizing is statistically significant for growers not covered by the PR (including those with a qualified exemption) and covered growers, with covered growers more likely to sanitize more frequently.

Toilets and Handwashing Sinks

The Produce Rule requires that growers provide hygienic toilet and handwashing facilities for all employees and visitors. Toilets must be regularly serviced, stocked, cleaned, and readily accessible to employees and visitors, including harvest crews in the field. Handwashing facilities must also be accessible and provide sanitary soap, water, and means of drying hands. Water and towel waste must be disposed of appropriately to avoid contamination of produce or agricultural water sources. Employees are required to use hygienic handwashing and drying practices.

Figure 23
Sanitizing schedule by Produce Rule (PR) and size for all growers who use harvest, field pack, and packing house equipment, tools, or bins, 2015/16



PR coverage and size

Notes: The sample consists of 3,368 growers who use harvest or field packing tools, harvest or field packing machinery, packing house tools, postharvest machinery and work surfaces, harvest bins, and transportation bins. The figure shows respondents' most frequently reported cleaning of multiple items. See detailed data for this figure in appendix table C-14.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

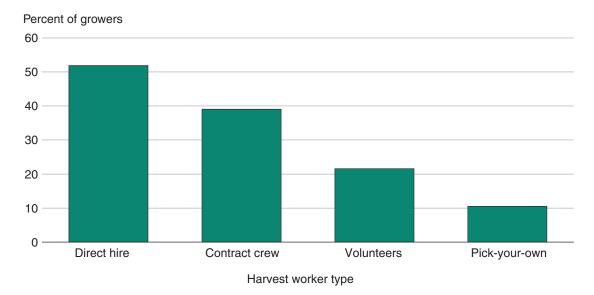
The PR's requirements surrounding harvest workers' facilities apply to the 3,897 growers who reported using harvest workers. Growers could report using multiple types of harvest workers and most frequently hired directly (51.9 percent), followed by harvest crews contracted from a third party (39.1 percent), then unpaid family or volunteer harvest workers (21.6 percent), and finally pick-your-own harvest workers (10.5 percent) (fig. 24).

While the PR stipulates that toilets and handwashing facilities must be "readily accessible," a specific distance is not prescribed. Survey response was based on the number of pairs of toilets and sinks provided to harvest workers within 0.25 mile of where they are working (OSHA, 2011).²⁰ Among growers who reported using labor for harvesting, 83.1 percent already met the Occupational Safety and Health Administration (OSHA) requirement of toilets within a quarter mile of the field for their harvest employees while 16.9 percent did not. The share of growers who had toilet facilities ranged from 95.7 and 94.4 percent for large and very large growers to as low as 67.9 percent among those not covered by the PR (fig. 25).

¹⁹There were 723 growers who did not report using harvest workers (16 percent of the sample). It is not possible to determine if these growers were using mechanical harvesting or growing crops under contract that included harvest by the contracting firm. Of growers who did not report using harvest workers, 51 percent sold more than 90 percent of their crop acres to processing, and 70 percent of these processed crops were sweet corn, snap beans, and green peas, all of which are commonly machine harvested. Another 41 percent of growers who did not report using harvest workers did not pack or package any produce on their operation and may have grown produce harvested by the shipper or buyer. These two groups made up 92 percent of growers who did not report using harvest workers.

²⁰In the survey, growers were asked about toilets/portable toilets and sinks separately. Because the answers were almost identical, we combine them into toilet/sink pairs.

Figure 24
Harvest worker types for growers with harvest workers, 2015/16 ¹

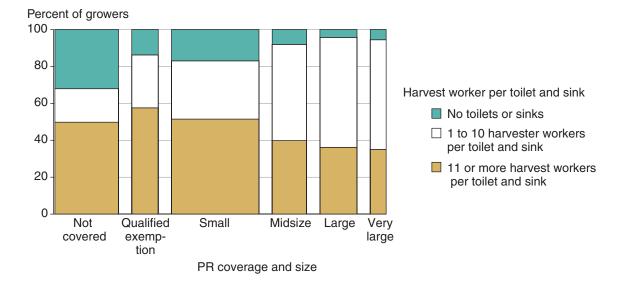


¹Not all growers reported using harvest workers.

Notes: The sample consists of 3,897 growers covering 1,031,010 acres. Growers could report multiple types of harvest workers used.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Figure 25
Number of harvest workers per toilet and sink pair by Produce Rule (PR) coverage and size for growers with harvest workers, 2015/16



Notes: The sample consists of 3,897 growers covering 1,031,010 acres. We make an assumption for 10 growers who report having sinks and toilets but do not report the number to have 1 of each. We also make an assumption for 36 growers who report having harvest workers but do not report the number to have 11 or more harvest workers per toilet and sink. See detailed data for this figure in appendix table C-15.

We look at the number of workers per toilet and sink pair to see patterns in use. More than half of growers who had facilities within 0.25 mile of where harvest work occurred had 1 to 10 workers for each toilet and sink pair. With fewer harvest workers, the small covered growers were more likely than larger growers to have 1 to 10 harvest workers per toilet and sink pair. Larger covered growers were more likely than smaller growers to have 11 or more workers per toilet and sink pair. We cannot determine the adequacy of the reported facilities to meet all of the PR's requirements, but (based on OSHA guidelines) it seems reasonable to assume that the majority of covered growers who already had toilet and sink facilities would not have to make drastic changes to comply with the PR.

Conclusions

Enacted in 2011, the Food Safety Modernization Act (FSMA) has been the most significant change to U.S. food safety laws in 70 years. When fully implemented, FSMA will affect every stage of the food production and marketing system, shifting the policy focus away from reaction to foodborne-illness outbreaks and toward risk-based preventive action. To more fully understand the economic impacts of the FSMA Produce Rule (PR) on the U.S. produce industry, U.S. Department of Agriculture's (USDA) Economic Research Service (ERS), in conjunction with National Agricultural Statistics Service (NASS), collected information on the food safety practices of produce growers before the PR's implementation. The data provided in this report, USDA's first update of national food safety practices since 1999, can inform opportunities for training, implementation of food safety practices, and perhaps, future rules or guidance as the PR implementation moves forward.

Survey results reveal that many covered growers already had some food safety practices in place: about 50 percent of growers had a food safety person who often had to split his or her time among other activities; about 50 percent of growers provided some level of food safety training for their harvest workers; the majority of growers tested preharvest, harvest, and postharvest water; the majority of preharvest ground water was tested frequently enough, while the majority of surface water was not. Most growers did not use manure products, and most growers did not perform a preharvest assessment for animal contamination. However, most growers did monitor for animal intrusion and use some type of intrusion prevention. A majority of growers performed cleaning activities daily; all growers cleaned more frequently than they sanitized; and the majority of growers provided toilets and sinks to their harvest workers. Larger, covered growers consistently showed higher levels of adopting food safety practices than smaller, covered growers did. All farms may have needed to make some changes to meet the PR's standards; however, generally, smaller farms needed to make more changes than larger farms. The share of acres for which growers were using some food safety practices was much greater than the share of growers because large growers who controlled large acreages were more likely to have food safety practices.

Growers not covered by the PR were often the least likely to have food safety practices in place that would be considered acceptable under the rule. However, growers with a qualified exemption were more likely than the small growers who would be covered to have food safety practices that met PR requirements. In both cases, growers who would not be required to adopt new food safety practices under the PR had done so anyway, possibly due to market forces already in place. This topic may merit further research.

At the time of the survey, covered growers performed many food safety activities at a higher level than did growers who would not be covered or had a qualified exemption. For example, more covered growers already had at least one food safety person (66 percent of very large and 20 percent of uncovered growers); tested the direct contact water they applied preharvest in the field (75 percent of very large and 43 percent of uncovered); did not use untreated manure (98 percent of very large and 94 percent of not covered); monitored for animal intrusion (51 percent of very large and 14 percent of uncovered); and maintained toilet and sink facilities for their harvest workers (95 percent of very large and 68 percent of not covered).

Survey results provide a general idea of how much growers spent on some of the food safety practices already in place. (These should not be interpreted as the cost to meet the standards of the PR or a complete measure of costs for food safety practices.) Very large covered growers spent about 16 times more on food safety practices measured in this report than growers not covered by the PR.

The costs for growers with audits may serve as an imprecise proxy for expenses for growers who already have had sufficient, or nearly sufficient, food safety practices to meet the standards of the PR. Audited growers spent on average about 2 to 10 times more on food safety than growers without audits, depending on their PR coverage and size category. The lower costs for those without audits indicated a potential need to implement additional food safety practices to meet the PR's standards. Without accounting for number and type of private audits, marketing channel, or packing activities, we found that large growers—not very large growers—exhibited the lowest cost of measured food safety activities per acre, and growers not covered by the PR exhibited the highest cost per acre.

The summary statistics presented in this report raise many questions for future research and analysis. For example, what drives the adoption of food safety practices? How do retailer, food-service, and processor/buyer demands for food safety audits influence the adoption of practices and their related costs? How do practices vary by crop or geography? This survey provides a rich database—a foundation that can be used to further analyze the diversity of food safety practices within U.S. agriculture.

References

- Adalja, A., and E. Lichtenberg. 2018. "Produce Growers' Cost of Complying with the Food Safety Modernization Act," *Food Policy* 74: 23-38.
- Becot, F., V. Nickerson, D. Conner, and J. Kolodinsky. 2012. "Costs of Food Safety Certification on Fresh Produce Farms in Vermont," *HortTechnology* 22(5): 705-14.
- Calvin, L., H. Jensen, K. Klonsky, and R. Cook. 2017. Food Safety Practices and Costs under the California Leafy Greens Marketing Agreement, EIB-173, USDA, Economic Research Service.
- Calvin, L. 2013. *The Food Safety Modernization Act and the Produce Rule, Vegetable and Pulses Outlook*, VGS-353-SA2, USDA, Economic Research Service.
- Calvin, L. 2003. "Produce, Food Safety, and International Trade: Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce," in *International Trade and Food Safety: Economic Theory and Case Studies*, AER-828, J. Buzby (ed). USDA, Economic Research Service.
- Cohen, N., C. Hollingsworth, R. Olson, M.J. Laus, and W. Coli. 2005. "Farm Food Safety Practices: A Survey of New England Growers," *Food Protection Trends* 25(5): 363-70.
- Hardesty, S., and Y. Kusunose. 2009. "Growers' Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs," UC Small Farm Program Research Brief, University of California, Davis, California.
- Hoffmann, S., M. Batz, and J. Glenn Morris Jr. 2012. "Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States Due to 14 Foodborne Pathogens," *Journal of Food Protection* 75(7): 1291-1302.
- Hoppe, R., and J. MacDonald. 2016. *America's Diverse Family Farms*, 2016 Edition, EIB-164, USDA, Economic Research Service.
- Hultberg, A., M. Schermann, and C. Tong. 2012. "Results from a Mail Survey to Assess Minnesota Vegetable Growers' Adherence to Good Agricultural Practices," *HortTechnology* 22(1): 83-88.
- Lichtenberg, E., and E. Tselepidakis Page. 2016. "Prevalence and Cost of On-Farm Produce Safety Measures in the Mid-Atlantic," *Food Control* 69: 315-323.
- Marine, S., D. Martin, A. Adalja, S. Mathew, and K. Everts. 2016. "Effect of Market Channel, Farm Scale, and Years in Production on Mid-Atlantic Vegetable Producers' Knowledge and Implementation of Good Agricultural Practices," *Food Control* 59: 128-138.
- Painter, J., R. Hoekstra, T. Ayers, R. Tauxe, C. Braden, F. Angulo, and P. Griffin. 2013. "Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States, 1998-2008," *Emerging Infectious Disease* 19(3): 407-415.
- Prenguber, B., and A. Gilroy. 2013. A First Look at Produce Safety Costs on Oregon's Small and Medium Fresh Fruit and Vegetable Farms, Oregon Public Health Institute.

- Rangarajan, A., M. Pritts, S. Reiners, and L. Pedersen. 2002. "Focusing Food Safety Training Based on Current Grower Practices and Farm Scale," *HortTechnology* 12(1): 126-31.
- Scallan, E., P. Griffin, F. Angulo, R. Tauxe, and R. Hoekstra. 2011. "Foodborne Illness Acquired in the United States—Unspecified Agents." *Emerging Infectious Disease* 17(1):16-22.
- Stenzel, T. United Fresh Produce Association. March 11, 2009. "Prepared Statement Before the U.S. House of Representatives Committee on Health," pp. 73-89.
- Sullins, M. 2014. "Understanding the Costs of On-farm Food Safety," Colorado State University Extension.
- Tootelian, D. 2008. "California Leafy Green Products 2007 Signatory Survey Summary Report of Findings."
- U.S. Department of Agriculture, National Agricultural Statistics Service. 2017a. "2016 Agricultural Chemical Use Survey: Vegetable Crops, NASS Highlights," No. 2017-4, Washington DC, July.
- U.S. Department of Agriculture, National Agricultural Statistics Service. 2017b. "Statistical Methodology: Vegetable Chemical Usage," Washington DC, July.
- U.S. Department of Agriculture, National Agricultural Statistics Service. 2016a. "2015 Agricultural Chemical Use Survey: Fruit Crops, NASS Highlights," No. 2016-7, Washington DC, August.
- U.S. Department of Agriculture, National Agricultural Statistics Service. 2016b. "Statistical Methodology: Fruit Chemical Usage," Washington DC, August.
- U.S. Department of Agriculture, National Agricultural Statistics Service. 2015. "2012 Census of Agriculture: Specialty Crops." Volume 2, Part 8. Washington DC, February.
- U.S. Department of Agriculture, National Agricultural Statistics Service. 2001. "1999 Fruit and Vegetable Agricultural Practices." Washington DC, June.
- U.S. Department of Labor, Occupational Safety and Health Administration (OSHA). 2011. "Field Sanitation Standard for Agriculture," 29 Code of Federal Regulations 1928.110.
- U.S. Food and Drug Administration. 2018. "FSMA Final Rule on Produce Safety" fact sheet.
- U.S. Food and Drug Administration. 2017a. "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know about the FDA Regulation: Guidance for Industry: Small Entity Compliance Guide."
- U.S. Food and Drug Administration. 2017b. "Equivalent Testing Methodology for Agricultural Water."
- U.S. Food and Drug Administration. 2017c. "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E," Proposed Rule, November.
- U.S. Food and Drug Administration. 2017d. "FDA Considering Simplifying Agricultural Water Standards," November 17.

- U.S. Food and Drug Administration. 2015a. "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."
- U.S. Food and Drug Administration. 2015b. "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Final Regulatory Impact Analysis."
- U.S. Food and Drug Administration. 2015c. "Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce."
- U.S. Food and Drug Administration. 1998. "Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables."

Appendix A - Survey Details

USDA, National Agricultural Statistics Service (NASS) fields its annual Chemical Use Survey to fruit and vegetable growers on an alternating-year basis—to fruit growers one year, to vegetable growers the next. Each year, it targets different States and commodities, so not all produce growers are potentially in the surveys. NASS aims to achieve 80-percent coverage levels for target commodities and uses the amount of targeted crops grown and a grower's inclusion in previous surveys to determine the probability that it will contact the grower (USDA, NASS, 2016b; USDA, NASS, 2017b). Both surveys were voluntary. In 2015-16, NASS sent a total of 14,046 surveys; 9,308 produce growers participated in the 2015 Fruit Chemical Use Survey and the 2016 Vegetable Chemical Use Survey; and 4,618 growers completed the ERS/NASS Produce Grower Food Safety Practices Surveys, which were included as an addendum to both surveys, for an overall response rate of 32.9 percent. 22

The 2015 Fruit Chemical Use Survey included 12 U.S. States, and the 2016 Vegetable Chemical Use Survey sample included an additional 7 States (fig. A-1, table A-1). California growers made up 27.3 percent of the sample, followed by Michigan, Oregon, and Washington. Table A-1 also compares growers in the ERS/NASS Produce Grower Food Safety Practices Surveys to those of the 2012 Census of Agriculture (USDA, NASS, 2015). States that represented a fairly large portion of growers in the census—such as California, Florida, Pennsylvania, and Washington—had similar coverage in the ERS/NASS survey. However, some States, including Michigan, Minnesota, New Jersey, and Oregon, were somewhat oversampled in the ERS/NASS survey.

While each Chemical Use survey asked about chemicals only on the target fruit or only on the target vegetables in a specific year, the food safety practice addendum asked growers to consider all fruit and vegetables on their operation in their responses. As a result, the food safety practice results covered crops beyond those on the target list for the 2015-16 Chemical Use surveys. We aggregate grower responses from both years into a single sample.²³ While growers in 2016 would have had 1 more year to adopt new food safety practices, aggregating both years of data provides a measure of average practices over the 2-year period prior to the implementation of the Food Safety and Modernization Act's Produce Rule (PR).

Among the growers in the ERS/NASS survey, stone fruit, apples/pears, and squash/pumpkins are the three most common groups of produce commodities grown (fig. A-2).²⁴ When looking at acres grown (including more than one crop over a season on the same acreage—double cropping), grapes, citrus, and leafy greens are the top three commodity groups (fig. A-3). Fifteen point two percent of growers in the sample grew less than 10 acres of produce crops; 44.5 percent grew 10 to less than

²¹The sample was drawn using a "Multivariate Probability Proportional to Size" design.

²²The response rate was 64.7 percent in the Fruit Chemical Use Survey and 69.9 percent in the Vegetable Chemical Use Survey.

²³We treat the sample as if it were sampled with replacement and included both sets of responses from the 86 growers who appeared in both years (1.9 percent of the sample). This assumes that those 86 growers were not dramatically different from all other growers sampled in the survey. Growers who appeared in both years were in a variety of States and a variety of coverage and size categories.

²⁴In the survey, growers were able to list the top five crops grown. There were 45.5 percent of growers who listed a single commodity; 39.1 percent who listed between two and four; and 15.4 percent who listed five commodities (although they may have had more than five).

100 acres; 35.2 percent grew 100 to less than 1,000 acres; and 5.1 percent grew 1,000 acres or more (fig. A-4). The sample ranges from those with less than \$25,000 in annual average produce sales over the last 3 years to those with \$40 million or more in sales (fig. A-5).²⁵

Table A-1
States where produce growers were located, ERS/NASS Produce Grower Food Safety
Practices Surveys compared to Census of Agriculture

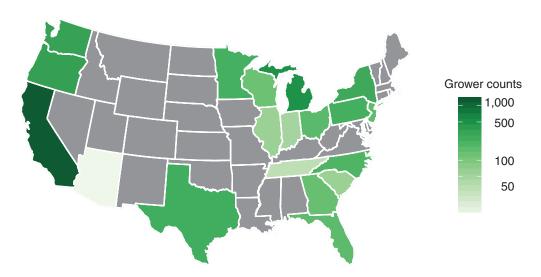
	ERS/NASS Pi	oduce Grower Food Sa	afety Practices Surveys	2012 Census of Agriculture
State	Year	Count	Percent	Percent
Arizona	2016	11	0.2	1.5
California	2015/16	1,263	27.3	24.0
Florida	2015/16	163	3.5	5.1
Georgia	2015/16	141	3.1	2.7
Illinois	2016	58	1.3	1.3
Indiana	2016	48	1.0	1.1
Michigan	2015/16	499	10.8	2.9
Minnesota	2016	231	5.0	2.1
New Jersey	2015/16	158	3.4	1.1
North Carolina	2015/16	203	4.4	3.1
New York	2015/16	284	6.1	3.6
Ohio	2016	167	3.6	2.2
Oregon	2015/16	349	7.6	3.5
Pennsylvania	2015/16	233	5.0	4.0
South Carolina	2015/16	59	1.3	1.4
Tennessee	2016	30	0.6	1.1
Texas	2015/16	248	5.4	4.1
Washington	2015/16	342	7.4	4.7
Wisconsin	2016	131	2.8	2.4
Other				28.0
Sum		4,618	100.0	100.0

Note: The sample consists of 4,618 growers and 1,262,604 acres. -- indicates data not applicable.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016 and the 2012 Census of Agriculture (USDA, NASS 2015).

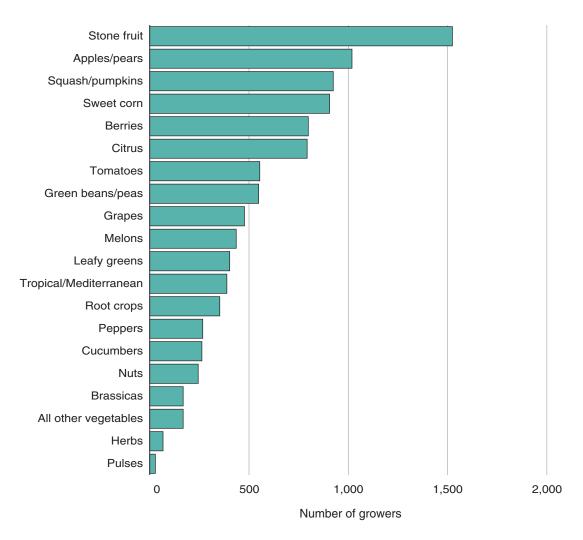
²⁵Sales revenue is often a sensitive topic, and 166 growers did not respond to the sales question (3.6 percent of the sample). Of these, we classify 21 growers as not covered by the PR based on growing commodities that are not commonly consumed raw or commodities that will be processed with a kill step—i.e., cooking, pasteurization, or another process that has been scientifically validated to reduce microbial contamination to a specified level. We classify four growers as eligible for a qualified exemption. We classify coverage and sales levels for the remaining 141 growers by comparing the acres grown of their top crop to the average acreage within sales levels of other growers with the same top crop. We classify growers imputed to be very small as not covered, and we classify growers imputed to be small and who sell more than 50 percent direct to consumers as having a qualified exemption. In Appendix D, we compare sample statistics including and excluding these 166 observations (appendix table D-1 to appendix table D-7). For all measures, percentages of total sample differed by less than 1 percent.

Figure A-1
States where surveyed produce growers were located, ERS/NASS Produce Grower Food Safety Practices Surveys, 2015/16



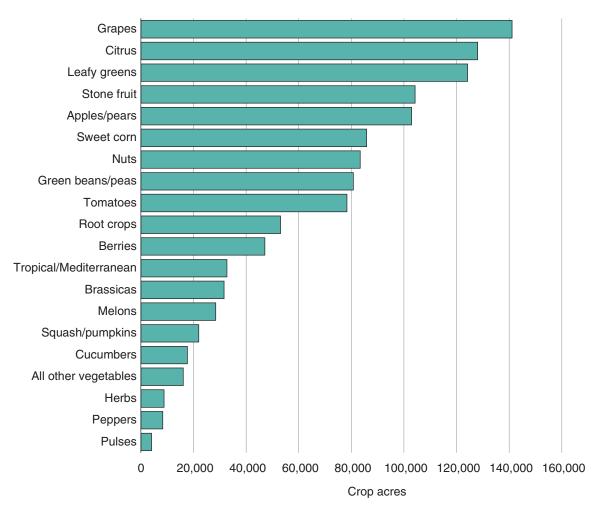
Note: The sample consists of 4,618 growers covering 1,262,604 acres. See detailed data from this figure in table A-1. Growers in States marked in dark gray were not surveyed.

Figure A-2 Growers of commodity groups, 2015/16



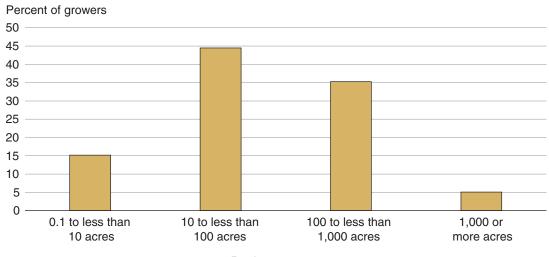
Note: The sample consists of 10,333 grower-commodity observations (growers may be counted in more than one commodity group). Stone fruit contains apricots, cherries, sweet cherries, tart cherries, nectarines, peaches, plums, pluots, and prunes. Apples/pears contains apples, currants, and pears. Squash/pumpkins contains gourds, pumpkins, and squash. Sweet corn contains only itself. Berries contains berries, blackberries, blueberries, cranberries, black raspberries, red raspberries, raspberries, and strawberries. Citrus contains grapefruit, lemons, oranges, navel oranges, Valencia oranges, tangelos, and tangerines. Tomatoes contains only itself. Green beans/peas contains snap beans, succulent beans, and peas. Grapes contains grapes, juice grapes, raisin grapes, table grapes, wine grapes, and persimmons. Melons contains cantaloupe, honeydew, and watermelons. Leafy greens contains Chinese cabbage, head cabbage, collard greens, kale, lettuce, mustard greens, spinach, and turnip greens. Tropical/Mediterranean contains avocados, dates, figs, kiwis, olives, and pomegranate. Root crops contains beets, carrots, chufas, daikon radishes, dry onions, bulb onions, potatoes, radishes, rutabagas, sweet potatoes, and turnips. Peppers contains bell peppers, pimientos, and other peppers. Cucumbers contains cucumbers and cucurbits. Nuts contains almonds, chestnuts, hazelnuts, macadamia, peanuts, pecans, pistachios, and walnuts. Brassicas contains broccoli, Brussels sprouts, and cauliflower. All other vegetables contains artichokes, asparagus, celery, eggplant, green onions, mushrooms, okra, miscellaneous vegetables, and rhubarb. Herbs contains cilantro, garlic, ginger root, herbs, horseradish, mint, miscanthus, parsley, and sage. Pulses contains castor beans, fava beans, lima beans, and dry beans.

Figure A-3 **Acres of commodity groups, 2015/16**



Note: The sample consists of 1,198,860 acres reported for specific commodities. Stone fruit contains apricots, cherries, sweet cherries, tart cherries, nectarines, peaches, plums, pluots, and prunes. Apples/pears contains apples, currants, and pears. Squash/pumpkins contains gourds, pumpkins, and squash. Sweet corn contains only itself. Berries contains berries, blackberries, blueberries, cranberries, black raspberries, red raspberries, raspberries, and strawberries. Citrus contains grapefruit, lemons, oranges, navel oranges, Valencia oranges, tangelos, and tangerines. Tomatoes contains only itself. Green beans/peas contains snap beans, succulent beans, and peas. Grapes contains grapes, juice grapes, raisin grapes, table grapes, wine grapes, and persimmons. Melons contains cantaloupe, honeydew, and watermelons. Leafy greens contains Chinese cabbage, head cabbage, collard greens, kale, lettuce, mustard greens, spinach, and turnip greens. Tropical/Mediterranean contains avocados, dates, figs, kiwis, olives, and pomegranate. Root crops contains beets, carrots, chufas, daikon radishes, dry onions, bulb onions, potatoes, radishes, rutabagas, sweet potatoes, and turnips. Peppers contains bell peppers, pimientos, and other peppers. Cucumbers contains cucumbers and cucurbits. Nuts contains almonds, chestnuts, hazelnuts, macadamia, peanuts, pecans, pistachios, and walnuts. Brassicas contains broccoli, Brussels sprouts, and cauliflower. All other vegetables contains artichokes, asparagus, celery, eggplant, green onions, mushrooms, okra, other vegetables, and rhubarb. Herbs contains cilantro, garlic, ginger root, herbs, horseradish, mint, miscanthus, parsley, and sage. Pulses contains castor beans, fava beans, lima beans, and dry beans.

Figure A-4 **Produce acres grown, 2015/16**

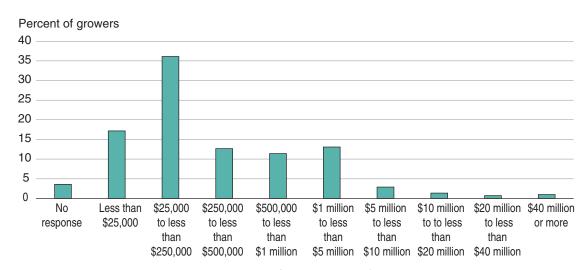


Produce acres grown

Note: The sample consists of 4,618 growers covering 1,262,604 acres.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Figure A-5
Three-year average annual gross value of all produce sales, 2015/16



Average gross sales

Note: The sample consists of 4,618 growers covering 1,262,604 acres.

To investigate the representativeness of the ERS/NASS Produce Grower Food Safety Practices Surveys, we compare its results with those in FDA's 2015 Final Regulatory Impact Analysis (RIA) (USDA, NASS, 2015b). FDA derived its estimates from 2012 Census of Agriculture microdata, which should be representative of produce farms in the United States (table A-2). The size and PR-coverage category distributions are different in the 2012 Census of Agriculture as analyzed by FDA and the ERS/NASS survey. (The definitions of sizes in the ERS/NASS food safety practice survey differ in some cases by \$1, which should not substantially impact comparisons.)

The objective of a census is to gather information on every grower, no matter how small, while the objective of a survey is to gather enough information to describe the population composed of a wide variety of growers. The ERS/NASS survey captures a variety of growers by PR coverage and size with a focus on growers who made up the largest share of the market. The FDA analysis of the census data showed that 61.9 percent of growers would not be covered under the PR because they had sales of \$25,000 or less; the ERS/NASS survey shows 18.2 percent of growers with less than \$25,000 in sales. In every other category, however, the ERS/NASS survey has a larger percent of growers than the census. The ERS/NASS survey shows 29.8 percent of covered growers with sales of \$500,000 or more, compared to 6.8 percent in the census. The ERS/NASS survey shows 64.8 percent of growers and 89.9 percent of acres covered by the PR. In comparison, the FDA Final Regulatory Impact Analysis, based on the 2012 Census of Agriculture, found that 28.9 percent of growers would be covered by the PR accounting for 70 percent of produce acres (FDA, 2015b).

Table A-2

Produce Rule coverage, ERS/NASS Produce Grower Food Safety Practices Surveys compared to FDA's Final Regulatory Impact Analysis

•	• , ,	•			
	ERS/NASS Produce Grower Fo Practices Survey	od Safety	FDA's Final Regulatory Impact Analysis		
Coverage	Produce sales	Growers	Produce sales	Growers	
	(Average over last 3 years)	Percent	(Average over last 3 years)	Percent	
Not					
covered	Less than \$25,000	18.2	\$25,000 or less	61.9	
	\$25,000 to less than \$250,000	6.7	Over \$25,000 but no more than \$250,000	5.0	
	\$250,000 to less than \$500,000	2.2	Over \$250,000 but no more than \$500,000	1.5	
Qualified					
exempt	\$25,000 or more in produce sales and less than \$500.000 in food sales	8.1	Over \$25,000 in produce sales and no more than \$500,000 in food sales	2.7	
Covered					
	\$25,000 to less than \$500,000	35.0	Over \$25,000 but no more than \$500,000	22.1	
	\$500,000 and up	29.8	More than \$500,000	6.8	
Total		100.0		100.0	
		•	·	*	

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016, U.S. Food and Drug Administration (FDA, 2015b).

MICROBIAL FOOD SAFETY PRACTICES

F

The next few pages contain questions that ask about your operation's total produce acreage, in addition to the fruit covered previously, regardless of the state where that acreage is located. *Exclude* any acreage outside of the U.S. For the purposes of this part of the survey, produce **includes**: fruit, berries, vegetables, herbs, tree nuts, dry beans, peas and lentils, peanuts, sprouts, and mushrooms. These questions only ask about food safety practices with respect to microbial contamination.

		Acres
1.	In 2015, how many acres on your operation were used to grow produce ? (<i>Include</i> each acre only once	700
even if 1	multiple crops were grown on it.).	
2.	Including multi-cropped acres, how many total acres of produce were grown on your operation	701
	in 2015?	

3. What produce crops grown on your operation made up the most acreage in 2015, and how were they sold? Report the top five crops starting first with the one that made up the most acreage in row (a).

1	2	3	3 Non Direct-to-Consumer		er Sales	
Crop	Acres (Include multi- cropped acres)	Direct-to- Consumer Sales (Percent)	4 Fresh market (Percent)	Fresh-cut market (Percent)	6 Processed market (Percent)	
702 a.	703	704 %	705 %	706 %	707 %	100%
710 b.	711	712 %	713 %	714 %	715 %	100%
716 c.	717	718 %	719 %	720 %	721 %	100%
722 d.	723	724 %	725 %	726 %	727 %	100%
728 e.	729	730 %	731 %	732 %	733 %	100%

4.	D	uring the three year period, 2012 th	rough 2014, w	hat was your o	peration's average a	nnual gross value of	all produce sales?
	740	1 ☐ Less than \$25,000	4 🔲 \$500,000	to \$999,999	7 🔲 \$10,00	0,000 to \$19,999,999	
		2 \(\square\) \$25,000 to \$249,999	5 🔲 \$1,000,000	0 to \$4,999,999	8 🔲 \$20,00	0,000 to \$39,999,999	
		3 🗆 \$250,000 to \$499,999	6 🗆 \$5,000,000	0 to \$9,999,999	9 🔲 \$40,00	0,000 and above	
[If the	e val	lue of sales reported in Item 4 is lo	ess than \$500,	000, continue;	otherwise go to Ite	m 6]	
5.	D	uring the three year period, 2012 th	rough 2014, w	as your operati	on's average annual	gross value of	
food s	ales	less than \$500,000? Food includes	articles used f	or food or drin	k for humans or othe	er animals. 741	☐ Yes 3 ☐ No
						None	Acres
6.	ln	2015, how many of your operation	s produce acr	es were certifie	ed organic?		· <u> </u>
7.	In	2015, were commercia l livestock	located adjaces	nt to your prod	uce acreage on land:	:	
a.	Y	ou operate? (<i>Include</i> livestock on	your produce a	creage)		743 1	Yes 3 No
b.	So	omeone else operates?				744 1	Yes 3 No
8.	In	2015, which of the following activ	rities were com	pleted for your	operation's produce	e, and where were the	y done?
		1			2	3	4
					On your produce	Off your produce	Did you have an
		Activity			operation	Operation	ownership interest in this activity
				YES = 1	YES = 1	YES = 1	YES = 1
a.	U	-Pick		750	751		752
b.	Н	arvest		753	754		755
c.	Fi	ield Pack		756	757		758
d.	Pa	ack (other than field pack)		759	760	761	762

e.	Cool	763	764	765	766	
f.	Wash	767	768	769	770	
g.	Hold/Store/Warehouse	771	772	773	774	
h.	Fresh Cut	775	776	777	778	
i.	Other processing (freezing,	779	780	781	782	
	canning, juicing, etc.)					
).	Excluding any direct-to-consumer sales, do you sel	ll your own pro	duce to retailers, foo	dservice, 783		
wholesa	ilers, terminal markets, etc, instead of letting another	r firm (shipper,	sales agent, markete	r, etc.) sell	☐ Yes 3	i
for you?)				No	
10.	Do you have a food safety plan that covers your pro-	oduce operation	n in 2015?			
	784 1 Yes – Continue 3 No – 0	Go to Item 12				
	1 100 Commune					
					Yes 3	i
1.	Is the food safety plan written?				_l No	
11.	In 2015, did your food safety plan cover all your pr	roduce commod	lities?			
	786 ₁ Yes – Go to Item 12 3 No –	Continue			Plans	
ı.	How many different food safety plans did you have	e for your produ	ace commodities in 2	2015?	787	
12.	Did you have any third party food safety audits tha	t covered your	produce operation in	2015?		
	788 1 Yes – Go to Item 13 3 No –	Continue		N/A	Year (YYYY)	
ì.	What was the most recent year you had a third part	y food safety a	udit that covered you	ır produce	789	
operatio	n?					
					Go to Item 16	

13.	Did the following types of microbial third party food safety audits cover your produce operation	n in 2015	?	
		790	1 Nes	3
a.	Produce farm/ranch (field) audit.			☐ No
		791	1 Yes	3
b.	Produce harvesting crew.			☐ No
		792	1 Yes	_
C.	Produce packinghouse.	702		∐ No
d.	Produce cooler	793	1 Yes	3 □ No
u.	110000000000000000000000000000000000000	794	₁ ☐ Yes	
e.	Other (Specify: ⁷⁹⁵)		1 100	☐ No
14.	How many of the following types of third party food safety audits covered your produce			
operatio	n in 2015?	None	Numb	er
a.				
ш.	Global Food Safety (GFS) initiative benchmark audit (Primus GFS, Safe Quality Food (SQF)		796	
	Global Food Safety (GFS) initiative benchmark audit (Primus GFS, Safe Quality Food (SQF) AP, CanadaGAP, British Retail Consortium (BRC))		796	
			796 797	
GlobalG b.	AP, CanadaGAP, British Retail Consortium (BRC))			
GlobalG b.	AP, CanadaGAP, British Retail Consortium (BRC))			
GlobalG b. (Primus,	AP, CanadaGAP, British Retail Consortium (BRC))		797	
GlobalG b. (Primus, c.	AP, CanadaGAP, British Retail Consortium (BRC))		797	
GlobalG b. (Primus, c.	AP, CanadaGAP, British Retail Consortium (BRC)). Other general private audit that is not benchmarked to the Global Food Safety initiative AIB, SCS, etc.). Addendum to standard audit for a particular buyer or processor. Stand-alone buyer-specific audit you pay for (excluding addendum).		797 798 799	
GlobalG b. (Primus, c. d.	AP, CanadaGAP, British Retail Consortium (BRC)). Other general private audit that is not benchmarked to the Global Food Safety initiative AIB, SCS, etc.). Addendum to standard audit for a particular buyer or processor. Stand-alone buyer-specific audit you pay for (excluding addendum). California or Arizona Leafy Greens Marketing Agreement (LGMA) audit		797 798 799 806	
GlobalG b. (Primus, c. d. e.	AP, CanadaGAP, British Retail Consortium (BRC)). Other general private audit that is not benchmarked to the Global Food Safety initiative AIB, SCS, etc.). Addendum to standard audit for a particular buyer or processor. Stand-alone buyer-specific audit you pay for (excluding addendum). California or Arizona Leafy Greens Marketing Agreement (LGMA) audit. California Cantaloupe Advisory Board food safety standard audit.		797 798 799 806 807	
GlobalG b. (Primus, c. d. e. f. g.	AP, CanadaGAP, British Retail Consortium (BRC)). Other general private audit that is not benchmarked to the Global Food Safety initiative AIB, SCS, etc.). Addendum to standard audit for a particular buyer or processor. Stand-alone buyer-specific audit you pay for (excluding addendum). California or Arizona Leafy Greens Marketing Agreement (LGMA) audit. California Cantaloupe Advisory Board food safety standard audit. Tomato Food Safety Audit Protocol.		797 798 799 806 807	

i.	Other (Specify: 811)	810
15.	What was the total amount you paid for the third party food safety audits that covered your	

produce operation in 2015? (*Include* costs of belonging to CA and AZ LGMA and the CA Cantaloupe Advisory Board. *Exclude* the costs of preparing for audits and the costs of implementing changes afterwards. *Exclude* organic certification audits.).

	Doll	ars	
812			

16. Which of the following types of water were used on the production, harvest, and postharvest activities of your operation's produce in 2015? Use the response codes listed in the table at the bottom of the page.

1		2	3	4	5
		What is the	How often did you test the	What water	What did you
		largest source (in	water from this source in	standard did	use to treat this
Water Use		terms of volume)	2015 for microbial content	you consider	water in 2015?
water use		of water used for	(generic E. coli or other	acceptable?	
		this activity?	indicator)? If code 7 or 8,		
			go to column 5.		
		(See column 2 code		(See column 4	(See column 5
	YES = 1	below)	(See column 3 code below)	code below)	code below)
a. Water used during production that does	813	814	815	816	817
not touch the harvested part of the crop (furrow,					
drip, flood irrigation, etc.)					
b. Water used during production that touches	818	819	820	821	822
the harvested part of the crop (overhead irrigation;					
pesticide/fungicide applications; frost protection,					
etc.)					

c. Wa	ter used for harvest and postharvest	823	824	825	826	827
activities (in	cluding packing) where water touches					
the produce	or a food contact surface (hydrating,					
washing or o	cooling produce, cleaning food contact					
surfaces on t	tools or machinery)					

	Column 2		Column 3		Column 4		Column 5
	Water Source Code		Frequency of Testing Code		Water Test Standard Code		Treatment Code
1	Standing surface water	1	Once a year	1	Normal or expected range based	1	Chemical
	(ponds, lakes, reservoirs)	2	Once every four	on	historic water samples	2	Ultra violet light
2	Flowing surface water		months	2	EPA Recreational Water Standard	3	Filtration
(rive	ers, canals, streams, irrigation	3	Once every three		(1986 or 2012 standard)	4	N/A - didn't treat
ditch	nes)		months	3	Leafy Greens Marketing	5	Don't know
3	Ground water (wells)	4	Once every two	Agreem	ent	6	Other (Specify:
4	Public water system with		months		(LGMA) standard for water that)
pota	ble water	5	Once every month	does	not touch the harvested part of the		
5	Treated waste water	6	More often than once	crop			
6	Reclaimed tail water		a month	4	Maximum of 1,000 E.coli CFU/ml.		
7	Don't know	7	Water is never tested	5	Maximum of 500 E. coli CFU/ml.		
8	Other: (Specify:	8	N/A-Rely on someone	6	EPA drinking water standard		
	()		else's tests of this	which is			
			operation's water		no generic E. coli		
		9	Don't know	7	Reclaimed water standard		
		10	Other: (Specify:	8	Don't know		
)	9	Other: (Specify:		
)		

For items 17, 18, and 19, please consider all of the water sources used on your produce operation, not just the largest source of water.

						None	Number		
17.	How many total water tests for micro	xpect to		830					
conduct,	on your produce operation in 2015?	(Include a	ıll tests o	on all water sources)					
							Dollars		
18.	What will be the total cost of all water tests on all water sources conducted for microbial								
contami	nation on your produce operation in 2	015? (<i>Inc</i>	<i>lude</i> sup	oplies and lab costs (including	any shipping				
charges.))								
							Dollars		
19.	What will be the total cost in 2015 fo	or water tr o	eatment	s?			832		
	(Include supplies and lab costs (inclu	iding any	shipping	charges.)).					
20.	Were any of the following animal ma	nure prod	ucts app	lied to the produce acreage on	your operation	in 2015	?		
	1			2		3			
			Is t	he compost made using a					
			scienti	fically recognized, controlled	What docum	nentation	n do you have to		
			micro	bial process that is actively	indicate the	manure	was adequately		
				managed and meets	treated to	o reduce	e pathogens?		
			time/te	mperature requirements from					
	Manure Product $YES = 1$ EPA? Check al						at apply		
		833	834	ı 🗌 Yes	835 Time/tem	nperature	measurements 836		
a.	Composted manure made on your			3 No	Microbial tes	ting resu	llts		
farm				₂ Don't know	837 Other				
					838 None				

	839	840	
			841 Time/temperature measurements 842
			☐ Microbial testing results
		1 Yes	843 Certificate of Conformance
b. Composted manure purchased		3 No	844 Certificate of Analysis
from others		₂ Don't know	
			845 Comes from source approved by
			an organic certifying agent
			846 Other
			847 None
	848		
			849 Time/temperature measurements 850
			Microbial testing results
c. Manure treated with a physical or			851 Certificate of Conformance
chemical process (pasteurization, heat			852 Certificate of Analysis
drying, alkali stabilization, etc.)			853 Approved by an organic certifying
			agent
			854 Other
			855 None
	856		
d. Decomposed manure (stored or			857 Microbial testing results
aged in stacks)			858 Other
			859 None
	860		
			861 Microbial testing results
e. Raw manure			862 Other
			863 None
L			
21 1 2015	. 6.1	1 21 21 21	. 1 964
		roduce acres done within 3 days of har	
to identify potential microbial contamination	problems?		1 Yes 3 No

					Days				
22.	How many days long was the produce harvest season	n in 20	015?		865				
23.	In 2015, did this operation pack or package any produc	ce?							
	866 1 \square Yes – Continue 3 \square No – Go to Item 24	24			Days				
a.	How many days long was the produce packing season	n in 20	015?		867				
b.	In 2015, did this operation pack or package produce in	n the f	ĭeld?	868	Yes 3 No				
c.	In 2015, did this operation pack or package produce in a packing house or packing shed?								
	869 ₁ \square Yes – Continue 3 \square No – Go to Item 24								
d.	Which of the following best describes the structures w	here t	this operation packed	or packaged fresh					
	produce in 2015? (Check all that apply)								
87	70 1 A floor, such as a concrete slab, driveway, parkin	ng lot,	etc.						
	$_{2}$ \square A roof and a floor, such as a concrete slab								
	3 A floor, roof, and some walls or screening but no	ot an e	nclosed structure						
	4 Enclosed structure with openings, such as unscreen	ened o	doors or windows						
	₅ Completely enclosed structure								
	6 Other (Specify: 871)					
24.	Which of the following types of items that touched this	is crop	during the 2015 seas	on were used on this p	roduce operation? How				
often v	were the items cleaned and sanitized? (Exclude items use	ed dui	ring harvest or posthar	evest if this crop was c	ustom harvested or				
packed by someone else.)									
	1		2	3	4				
				How often is this item					
			How often is this item	sanitized?	Does this item contain any				
	Item		cleaned?	(disinfected)	food contact surfaces of				
			[Use Frequency Code	[Use Frequency Code	foam, cardboard, wood,				
			table below]	table below]	carpeting, or canvas that				
	YES =	= 1	(Code)	(Code)	contact the crop?				

		872	873	874	875	1 🗌 Yes	
						3 No	
a.	Tools used for harvesting and/or field packing					₂ Don't know	
		876	877	878	879	1 Yes	
b.	Machinery used for harvesting and/or field					3 No	
packing						₂ Don't know	
		880	881	882	883	1 Yes	
c.	Tools used during packing or handling in a					3 No	
packing	nouse					₂ Don't know	
d.	Fixed machinery and work surfaces in postharvest	884	885	886	887	1 Yes	
handling	(mechanical sorter, work surface, dunk tanks,					3 No	
flumes, p	produce-washing sinks, etc.)					₂ Don't know	
		888	889	890	891	1 Yes	
						3 No	
e.	Reusable containers or bins used during harvest					₂ Don't know	
		892	893	894	895	1 Yes	
f.	Reusable containers or bins used only to transport					3 No	
the crop	from the field to a packing house					₂ Don't know	
		Freque	ency Code				
1	- Daily 2 - Weekly 3 - Monthly 4 - One	ce a season	5 - N/A 6 - Never	7 - Other: (Specify)	
				No	one	Dollars	
25.	In 2015, what will be the total cost of cleaning	g and sanitiz	ing the (Item 24) items		г	896	
	25. In 2015, what will be the total cost of cleaning and sanitizing the (Item 24) items that touch the crop? (<i>Include</i> supplies.)						
26.	26. In 2015, did your operation have a designated person with the primary responsibility for microbial food safety?						
89	⁷ 1 ☐ Yes 3 ☐ No					n.	
			1 0 0 00150			Percent	
a.	What percent of this person's daily time was s	spent on foo	d safety in 2015?			898	

27. In 2015, how many other people (excluding the one reported in Item 26) were on your microbial food safety staff? (*Include* harvest foreman if they have an important role and staff involved in recordkeeping. *Exclude* managers and others who have only a small share of their time on food safety and are not primarily responsible for day-to-day food safety on your operation. *Exclude* people only involved in food quality or quality assurance activities.)

	Number	
910		

[If Item 27 equals zero, go to Item 28; otherwise continue.]

a. Of the (item 27) people on your food safety staff, how many were working full time on microbial food safety during the season?

911		

Number

28. In 2015, did you hire a paid outside microbial food safety consultant to develop or implement your food safety plan?.....

912		
	1 Yes	3 🔲 No

29. Which of the following types of people were used to harvest produce on your operation in 2015?

1	2	3	4	5
	How many of these	How many of these	What was the average	What were the total
	people were used	people were trained on	number of minutes of	training costs for visual
	to harvest produce	microbial food safety by	microbial food safety	aids, signage, notebooks,
	on your operation	your operation in 2015?	training that your	software packages, and
	in 2015?	If contract crews are	operation provided for	hired trainers (instead of
People		trained by someone	these people in 2015?	your own staff trainers),
		else, exclude them		etc. for these people?
		-		Include costs to instruct
		[If zero, go to column 5]		customers at u-pick
				operations about safety
				while on your operation.
YES = 1	(Number)	(Number)	(Number)	(Dollars)

a.	Customer	913	914	915	916	917
	(e.g. Pick-your-own)					
b.	Unpaid labor including	918	919	920	921	922
family and volunteers						
c.	Direct hire	923	924	925	926	927
d.	Contract harvest crew	928	929	930	931	932

30. During the 2015 produce harvest season, did your operation provide toilets or hand washing sinks within one-quarter mile of the produce field for those harvesting produce? (Include portable facilities in the field, access to facilities in nearby buildings, and facilities for u-pick operations.)

	1		2	3
	Item	YES = 1	During the 2015 produce harvest season, how many of each facility were provided to harvesters within one-quarter mile of the produce field? (Number)	For how many days were these facilities provided to people harvesting produce? (Number)
a.	Toilet/Port-a-potty	933	934	935
b.	Hand washing sink	936	937	938

31.	Which of the follow	ving methods were used on your produce operation to reduce the potential of uncontrolled	water runoff into
the prod	luce fields in 2015?	Check all that apply.	

32.	—	•	Id to check for potential animal intru	_	947 ₁ Yes	
	939 Ditch	_	941 Vegetable buffer strip on pond 944 Drainage system	942 Evaporation pond		,

33. Which of the following methods were used on your produce operation to reduce potential animal intrusion into the produce fields in 2015? Check all that apply.

	948 Put up fencing around the fields
	949 Put up fencing around standing surface water
	950 Remove animal harborage and attractants (removing excess brush, old equipment, and cull piles)
	951 Trap or shoot animals
	952 Employ animal deterrents such as noise makers (including gunfire), Mylar strips, fake owls or coyotes
	and repellants
	953 Clear a buffer zone around your field to increase your ability to detect animal intrusion
	954 Other (Specify: 955)
34.	Have you heard of the Food Safety Modernization Act (FSMA) Proposed Rule for Produce Safety?
	956 1 ☐ Yes - Continue 3 ☐ No – Go to Conclusion
35.	Which of the following sources have you used for information on the Food Safety Modernization Act (FSMA) Proposed Rule
or P	Produce Safety? Check all that apply.
	957 Produce/agricultural news
	958 The FSMA legislation or proposed rules
	959 FDA listening sessions, public meetings, webinar, or FSMA website
	960 Produce Safety Alliance
	961 University training/extension/education meetings
	962 Commodity organization training/education meetings
	963 Neighbors or other growers
	964 Other (Specify: 965)

Appendix B – Food Safety Modernization Act's Produce Rule Coverage Details

The Food Safety Modernization Act's Produce Rule (PR) covers many growers and commodities but not all and exempts others. In some cases, our survey data exactly identify producers who must comply with the PR; in other cases, we make approximations (table B-1).

Grower Coverage

The PR does not cover growers with average produce sales of \$25,000 or less over the last 3 years. In our analysis, we approximated these growers as those with sales of less than \$25,000 (table B-2). This \$1 difference was due to the way we asked the question about this size group in our survey and should have had little impact on results.

Congress stipulated a qualified exemption for growers with average food sales of less than \$500,000 during the previous 3 years and with more than 50 percent of food sales going directly to qualified end users. Food sales could include other crop and livestock sales in addition to produce sales. Qualified end users are consumers (where the consumer is not a business) anywhere; or a restaurant or food retailer in the same State, on the same Indian reservation, or not more than 275 miles away. Growers with a qualified exemption do not have to comply with all the PR's technical requirements, but must meet modified requirements for labels or labeling and limited recordkeeping activities.²⁶

We categorize those who were likely to obtain a qualified exemption to be growers who averaged annual produce sales of \$25,000 or more and who had food sales of less than \$500,000 over the previous 3 years and have more than 50 percent of sales direct-to-consumers.²⁷ The only sales to qualified end users identified in our survey data were direct-to-consumer sales, which underestimates the number of growers and acres that were eligible for a qualified exemption. To approximate direct-to-consumer sales, the survey asked growers what share of the acreage of their top five produce crops was marketed through direct-to-consumer channels.²⁸

Commodity Coverage

The PR does not cover produce that is grown for personal consumption or consumption on the farm. It applies only to raw agricultural commodities (RACs), food in its raw or natural state, with some types of RACs not covered or exempt (discussed below).²⁹ Processed commodities are covered by other rules within

²⁶Growers must provide their customers with their business name and address at the point of sale.

²⁷The survey asked whether food sales were less than \$500,000 annually and the average annual gross value of produce sales. Only one grower reported \$500,000 or more in produce sales and less than \$500,000 in food sales. In this case, we use food sales, not produce sales, to determine whether this grower was eligible for a qualified exemption.

²⁸We asked about marketing channels only for the top five produce commodities, not all commodities, which may introduce some bias in the share of sales through any channel. Also, growers who sold more than half of their food directly to consumers on acres not reported in the top five produce crops are not grouped among those eligible for a qualified exemption. Using acres of a commodity sold directly to consumers, rather than the value of the commodity sold, may introduce measurement error to our qualified exemption classification. For example, a grower who sold a small acreage of a high-value crop directly to consumers and a large acreage of a low-value crop via another marketing channel may be incorrectly assigned to be covered. Among growers who sold directly to consumers, 69.7 percent sold more than half of their reported acreage via that channel.

²⁹A raw agricultural commodity (RAC) is defined as any food in its raw or natural state, including all fruit that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

FSMA. For example, growers who sell whole heads of lettuce are covered under the PR, but growers who package and sell bagged salads are covered by another FSMA rule.³⁰

Table B-1

Produce Rule (PR) coverage and survey approximations

sources of this table for official language and interpretation of the rule.

PR coverage rules	This report's approximation of PR coverage rules
Growers are not covered if they sell \$25,000 or less of produce on average for the past 3 years	Growers would not be covered if they had sold <i>less than</i> \$25,000 of produce on average for the past 3 years ¹
Growers are eligible for a qualified exemption if they average sales of more than \$25,000 in produce and less than \$500,000 in <i>food</i> per year and more than half of sales go directly to consumers or to restaurants/retail food establishments within the same State or within 275 miles ²	Growers would be eligible for a qualified exemption if they averaged sales of \$25,000 or more in produce and less than \$500,000 in <i>food</i> on average for the past 3 years and sold produce from more than half of the acres for their top five crops directly to "qualified end-users"
Produce commodities are not covered if grown for personal or onfarm consumption	Growers who only grew for personal or onfarm consumption were not sampled in the Fruit and Vegetable Chemical Use Surveys
Produce commodities are not covered if rarely consumed raw ³	Growers who <i>only</i> grew produce commodities rarely consumed raw were considered to be not covered
Produce commodities are exempt if processed with a kill step ⁴	Growers who <i>only</i> grew tomatoes, oranges, grapes for juice, or grapes for wine and 100 percent of acres go to processing were considered not covered growers ⁵

¹The survey asked whether growers had produce sales of less than \$25,000, not \$25,000 or less, which accounts for the different definitions of growers who are not covered due to size.

² The FDA defines "qualified end-users" to be "either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm or not more than 275 miles away." Growers who claim a qualified exemption are required to begin keeping documentation supporting their eligibility on January 26, 2016. See the Small Entity Compliance Guide (FDA, 2017a) for more information.

³FDA has identified the following produce commodities to be rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chick-peas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazel-nuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.

⁴FDA specifically refers to "commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions." FDA also requires growers to maintain written assurances that the sold commodity will undergo acceptable processing.

⁵ We are unable to distinguish between produce going through processing that involves a kill step and processing that does not. However, we are able to identify four commodities that when sent to processing are extremely likely to undergo a kill step: processing tomatoes overwhelmingly go to sanitized canning; processing oranges and juice grapes overwhelming go to pasteurized orange juice and pasteurized grape juice; and processing wine grapes overwhelmingly go to fermented wine. While we unavoidably underestimate the number of growers who will not be covered by the PR because their produce will go to processing with a kill step, we have accounted for some of the biggest processing crops that would fall under this case. In determining coverage, we also account for growers who grow combinations of "rarely consumed raw" produce commodities and processing commodities that will have a kill step that constitute 100 percent of their product. A handful of growers are determined to be not covered taking this into account.

Source: The general categories described in this table are derived from the "FSMA Final Rule on Produce Safety" factsheet, published on the Food and Drug Administration (FDA) website (FDA, 2018) and the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published in the Code of Federal Regulations (FDA, 2015a). Readers should refer to the original

³⁰A point of significant discussion during the drafting of the PR and the Preventive Controls Rule (officially the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food) was the definition of a farm versus a facility. Operations under the farm definition are covered under the PR, while operations under the facility definition are covered under the more strict Preventive Controls Rule. For the purposes of FSMA, the FDA defines farms to be grower operations where handling and processing is limited to drying/dehydrating, packaging/labeling, ripening, or repackaging produce commodities of which their own harvested produce makes up at least 50 percent.

Raw agricultural commodities that are not commonly consumed raw are not covered, based on the assumption that adequate cooking would kill any potential pathogens. Examples include potatoes and beets (see table B-1 for a complete list). A covered grower growing only commodities not commonly consumed raw would not have to comply with the PR. If growers have both covered and not covered commodities, FDA considers the grower to be covered but only with respect to the covered commodities. These growers are required to apply the PR food safety practices only to the covered commodities, although they may apply the practices to all commodities. In this analysis, we considered all of the acres of a covered grower to be covered, which overestimated covered acres.

The PR exempts produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions. For example, a fruit or vegetable juice that is pasteurized would have an adequate reduction in risk; therefore, the original whole fruit or vegetable would not be subject to the PR. The produce to qualify for the commercial processing exemption, the grower must: (1) disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is not processed to adequately reduce the presence of microorganisms of public health significance; and (2) obtain annual written assurance from the customer that will do the processing that it will reduce the presence of microorganisms of public health significance. This paperwork puts checks and balances in the system. The grower and processor have agreed in writing that the product (which is not required to comply with PR food safety requirements) will be processed and not be redirected to the fresh market.

While the survey provides information on whether an item is processed, it does not indicate the type of processing and whether it included a "kill step" (i.e., an adequate reduction in microbial contamination). As a result, we are unable to identify if a commodity on a particular farm would be exempt. However, four commodities are almost always processed with a kill step: processing tomatoes; oranges and grapes for juice; and wine grapes. If a grower produces only these products for processing, FDA still categorizes the grower as covered although the grower does not have to comply with any of the food safety practices except recordkeeping; in this analysis, we categorize the grower as not covered (table B-1). We underestimate the number of growers with commodities with a processing exemption.

In this analysis, three characteristics put a farm in the not covered category: all the grower's produce was rarely consumed raw; all the grower's produce was processed with a kill step; or the grower's 3-year average annual produce sales was less than \$25,000. A grower may have had more than one of these characteristics. For the purposes of this report, we group all growers who would not be covered into one category. Of all not covered growers: 56.5 percent sold less than \$25,000 of produce annually (if a grower was in this category and another, the grower was counted in the other category, which accounts for the difference in the number of growers in this category reported in table B-3 and B-2), accounting for only 7.5 percent of not covered acres, so they are much smaller, on average, than the other not covered growers (table B-3). Another 31.8 percent grew only produce that was not commonly consumed raw, accounting for 26.1 percent of not covered acres. The final 11.7 percent grew only oranges, juice grapes, wine grapes, or tomatoes going to processing (growers who also had produce not commonly consumed raw were counted here), accounting for 66.4 percent of not covered acres, which made them much larger than the average not covered grower.

³¹Juice is covered by the FDA Juice Hazard Analysis & Critical Control Points (HACCP) Rule.

Table B-2

Size and Produce Rule coverage of produce growers

				Cove	red		
		Qualified				Very	-
Sales	Not covered	exemption	Small	Midsize	Large	large	All
			Percent of growers				
Less than \$25,000	18.2						18.2
\$25,000 to less than \$500,000	6.7	8.1	35.0				49.7
\$500,000 to less than \$1 million	0.8			11.4			12.1
\$1 million to less than \$5 million	1.0				12.5		13.6
\$5 million or more	0.4					5.9	6.3
Growers	27.1	8.1	35.0	11.4	12.5	5.9	100.0
			Percent of acres				
Less than \$25,000	1.9						1.9
\$25,000 to less than \$500,000	2.0	1.1	11.4				14.5
\$500,000 to less than \$1 million	0.5			8.9			9.4
\$1 million to less than \$5 million	2.2				22.6		24.8
\$5 million or more	2.3					47.0	49.3
Acres	9.0	1.1	11.4	8.9	22.6	47.0	100.0

Note: The sample consists of 4,618 growers and 1,262,604 acres. -- indicates data are not applicable. Rows and columns do not necessarily sum to the totals because of rounding.

Sources: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table B-3

Composition of growers not covered by the Produce Rule

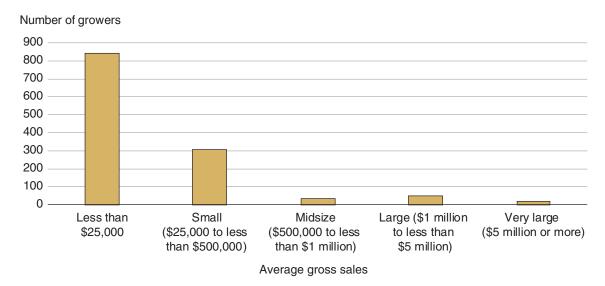
	Number of growers	Percent of growers	Total acres	Percent of acres
Produce grown is sold for less than \$25,000 annually	707	56.5	8,474	7.5
All produce grown not commonly consumed raw	398	31.8	29,546	26.1
All produce grown is for processing	146	11.7	75,099	66.4
Sum	1,251	100.0	113,119	100.0

Note: The sample consists of 1,251 growers and 113,119 acres.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

In terms of produce sales, 67.2 percent of not covered growers were very small; 24.7 percent were small; and the remaining were midsize, large, and very large (3.0, 3.7, and 1.5 percent, respectively) (fig. B-1). Growers who were not covered due to processing with a kill step had the highest share of growers with third-party audits, written safety plans, and awareness of the PR (table B-4). For very small farms with produce sales less than \$25,000, 23.1 percent had a food safety person.

Figure B-1
Size of growers not covered by the Produce Rule, 2015/16



Note: The sample consists of 1,251 growers covering 113,119 acres.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table B-4

Growers not covered by the Produce Rule (PR) with third-party audits, written food safety plans, awareness of the PR, and food safety person

	<\$25,000 annual sales	Not commonly consumed raw	For processing	All	
		Percent of growers	Percent of growers within column		
Third-party audit	6.1	6.5	11.6	6.9	
Written safety plan	13.0	16.6	41.1	17.4	
Aware of PR	39.9	36.7	49.3	40.0	
Food safety person	23.1	16.1	19.9	20.5	
All growers	56.5	31.8	11.7	100.0	

Note: The sample consists of 1,251 growers and 113,119 acres.

Appendix C – Detailed Data Tables

Table C-1
Third-party audits, written food safety plans, awareness of the Produce Rule (PR), and food safety person by size and Produce Rule coverage category for growers and acres

				Cov	ered		_				
	Not covered	Qualified exemption	Small	Midsize	Large	Very large	All	Sig. test ¹			
		Percent of growers within column									
Third-party audit	6.9	10.7	29.2	49.9	62.1	63.1	30.1	***			
Written safety plan	17.4	26.9	45.3	71.0	81.3	88.3	46.3	***			
Awareness of PR	40.0	72.5	59.3	65.9	74.9	81.8	59.2	***			
Food safety person ²	20.5	43.2	38.9	54.9	62.8	66.4	40.7	***			
All growers	27.1	8.1	35.0	11.4	12.5	5.9	100.0				
		Pe	ercent of a	cres within	column						
Third-party audit	7.1	12.2	25.9	41.2	54.7	66.9	51.2	***			
Written safety plan	53.6	30.3	41.9	64.4	78.1	91.9	76.5	***			
Awareness of PR	55.7	79.3	54.7	63.2	73.4	78.6	71.3	***			
Food safety person ²	40.3	47.3	32.9	45.4	58.7	57.9	52.4	***			
All acres	9.0	1.1	11.4	8.9	22.6	47.0	100.0				

Note: The sample consists of 4,618 growers and 1,262,604 acres.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²We assume nonresponses mean "no food safety person."

Table C-2

Measured food safety practice average annual cost (\$) per grower by size and Produce Rule
(PR) coverage for growers using each practice

	-			Cove	ered		
		Qualified				Very	Sig.
Food safety practice	Not covered	exemption	Small	Midsize	Large	large	test1
Per grower							
Audit fees	\$1,432	\$557	\$923	\$1,376	\$2,437	\$7,085	**
Water testing	265	130	206	438	655	2,150	***
Water treatment	3,331	217	1,189	1,568	1,596	22,864	
Harvest training	1,349	495	775	865	1,602	10,862	
Cleaning and sanitizing	1,253	1,256	1,145	1,829	6,744	20,826	***
Avg. cost per grower	1,889	1,426	1,761	2,922	7,936	30,673	***
Avg. cost per grower with audit	6,155	5,048	2,331	3,860	10,072	40,769	
Avg. cost per grower w/o audit	1,115	804	1,255	1,440	2,485	3,751	***
Per acre							
Audit fees	34	31	20	13	8	14	***
Water testing	13	7	5	4	2	3	***
Water treatment	55	8	17	14	6	17	*
Harvest training	28	11	17	10	6	15	
Cleaning and sanitizing	48	42	24	18	24	38	***
Avg. cost per acre	58	48	38	29	28	47	**
Avg. cost per acre with audit	117	137	46	39	35	61	*
Avg. cost per acre w/o audit	47	32	30	12	11	9	**
Per \$ sales							
Avg. cost per \$ sales	0.086	0.005	0.007	0.004	0.003	0.001	

Note: Averages in each cell are calculated using only growers who reported engaging in the associated food safety activity and may include some reports of zero cost. See appendix table C-3 for number of observations underlying the average in each cell. w/o = without.

^{1&}quot;Sig. test" is a t-test of means for growers not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

Table C-3

Number of respondents to cost questions by size and Produce Rule coverage and by audits

				Cove	red	
Food safety practices	Not covered	Qualified exemption	Small	Midsize	Large	Very large
Respondents						
Audit fees	64	34	392	222	298	127
Water testing	155	99	524	260	334	156
Water treatment	33	26	99	58	88	49
Harvest training	186	135	492	247	307	126
Cleaning and sanitizing	381	219	625	272	327	129
Total	514	266	957	418	476	209
Total with audit	79	39	450	256	342	152
Total without audit	435	227	507	162	134	57

Note: Numbers in each cell represent the number of survey respondents who answered each question. These numbers are meant to give context to the average costs presented in appendix tables C-2.

Table C-4

Percent of time, additional staff, and worker training by size and Produce Rule (PR) coverage by growers using practice and by acres

				Cove	red			
	Not	Qualified				Very		
	covered	exemption	Small	Midsize	Large	large	All	Sig. test
		Percer	nt of grower	s within colu	ımn			
Percent of time t	he one required		son spent o	n food safet	y^2			
76 to 100	11.8	9.6	9.4	9.3	14.3	37.4	13.3	**
26 to 75	8.2	10.3	11.5	10.7	17.8	23.6	13.2	***
1 to 25	80.0	80.1	79.1	80.1	67.9	39.1	73.5	***
All growers	13.5	8.6	33.5	15.5	19.2	9.6	100.0	
Number of additi	onal food safety	staff for those v	with more th	nan the one	required fo	od safety p	person ³	
6 or more	5.0	8.8	5.8	10.2	13.3	26.3	11.1	***
2 to 5	38.0	48.5	46.6	55.4	55.8	50.4	49.8	**
1	57.0	42.6	47.6	34.3	30.8	23.4	39.1	***
All growers	11.8	6.6	28.5	16.2	23.4	13.4	100.0	
Harvest workers	trained for grov	vers with harves	t workers4					
All	20.5	26.9	37.7	50.1	54.4	44.4	36.8	***
Some	5.2	17.6	7.8	11.8	11.9	22.4	10.0	**
None	74.3	55.5	54.5	38.1	33.7	33.2	53.2	***
All growers	24.4	9.1	33.9	12.5	14.0	6.1	100.0	
		Perce	ent of acres	within colur	nn			
Percent of time t	he one required	I food safety pers	son spent o	n food safet	y^2			
75 to 100	69.9	11.2	10.5	8.1	16.1	40.8	31.3	***
26 to 74	4.3	14.8	11.5	10.7	21.1	23.2	19.4	***
1 to 25	25.9	74.0	77.9	81.2	62.8	36.0	49.3	***
All acres	7.0	1.0	7.3	8.0	25.9	50.8	100.0	
Number of additi	onal food safety	staff for those v	with more th	nan the one	required fo	od safety p	person ³	
6 or more	0.4	13.6	11.7	9.5	16.1	29.0	22.0	***
2 to 5	73.7	46.6	48.8	55.1	57.6	54.5	56.2	***
1	25.9	39.8	39.5	35.5	26.4	16.6	21.8	***
All acres	6.8	0.6	5.1	5.5	22.9	59.1	100.0	
Harvest workers	trained for grov	vers with harves	t workers4					
All	26.6	26.7	35.5	40.0	49.3	31.9	36.8	***
Some	3.7	20.4	9.1	14.1	11.9	30.4	19.6	***
None	69.8	52.9	55.3	45.9	38.8	37.7	43.6	***
All acres	9.2	1.3	9.7	9.1	25.3	45.4	100.0	

Note: For "Percent of time the one required food safety person spent on food safety," the sample consists of 1,813 growers with a food safety person and 623,888 acres. For "Number of additional food safety staff for those with more than the one required food safety person," the sample consists of 1,024 growers with an additional food safety person beyond the required one person and 489,188 acres. For "Harvest workers trained for growers with harvest workers," the sample consists of 3,799 growers and 1,014,412 acres. Rows and columns do not necessarily sum to the totals because of rounding.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²We assume nonresponses to mean "don't know", which we exclude.

³We assume nonresponses to mean "0 additional food safety staff."

⁴We assume nonresponses to mean "0 harvest workers trained."

Table C-5

Preharvest water used for all growers by size and Produce Rule (PR) coverage

			Covered				_	
Preharvest water	Not covered	Qualified exemption	Small	Mid- size	Large	Very large	All	Sig. test ¹
	Percent of growers within column							
No water applied	38.6	19.5	18.9	9.7	5.0	6.6	20.8	***
Ground or surface water contacts produce	23.1	50.7	45.0	54.7	53.8	54.7	42.3	***
Other water ²	38.3	29.9	36.2	35.6	41.2	38.7	36.9	
All growers	27.1	8.1	35.0	11.4	12.5	5.9	100.0	
		Per	cent of a	cres w	ithin colu	mn		
No water applied	19.7	18.3	28.1	12.4	6.0	6.9	10.9	***
Ground or surface water contacts produce	15.4	56.4	43.2	54.5	52.4	58.4	51.1	***
Other water ²	64.8	25.3	28.7	33.1	41.6	34.7	38.0	***
All acres	9.0	1.1	11.4	8.9	22.6	47.0	100.0	

Note: The sample consists of 4,618 growers and 1,262,604 acres. Rows and columns do not necessarily sum to the totals because of rounding.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²"Other water" includes any source of water that does not contact produce, or public water or other water that contacts produce.

Table C-6
Test standard for untreated, preharvest ground or surface water that contacts produce and number of tests annually for untreated, harvest, and postharvest ground water for all growers

				Cov	ered			
		Qualified		Mid-		Very	-	Sig.
	Not covered	exemption	Small	size	Large	large	All	test ¹
		F	Percent of g	growers w	ithin colum	nn		
Test standard for untreated	d, preharvest gro	und or surface	water that o	contacts p	roduce			
EPA drinking water	13.0	15.8	16.2	16.5	19.7	12.6	16.0	
Other established numerical standard ²	5.9	5.6	10.7	16.9	21.3	37.8	13.6	***
Normal or within historic range	19.6	18.1	24.6	33.5	35.8	18.9	25.7	***
Don't know	19.6	14.7	21.8	23.6	17.7	24.3	20.5	***
No testing	41.9	45.8	26.7	9.5	5.5	6.3	24.2	***
All growers	15.7	10.3	38.9	14.0	14.7	6.4	100.0	
Untreated, harvest and po	stharvest ground	water tests pe	r year					
2 or more	6.2	9.0	11.2	19.0	32.7	60.7	15.7	***
1	38.4	41.8	56.6	61.0	49.0	21.4	48.7	***
Someone else tests	3.4	4.5	4.1	2.0	1.0	0.0	3.2	
Don't know/other	10.3	12.7	9.1	10.0	7.7	14.3	10.1	
Never	41.8	32.1	19.0	8.0	9.6	3.6	22.4	***
All growers	19.4	17.8	32.1	13.3	13.8	3.7	100.0	
			Percent of	acres with	hin columr	1		
Test standard for untreated	d, preharvest gro	und or surface	water that o	contacts p	roduce			
EPA drinking water	13.6	15.3	17.3	12.0	22.6	4.0	11.4	***
Other established numerical standard ²	7.0	8.6	11.0	12.8	18.7	41.3	27.9	***
Normal or within historic range	42.7	20.2	23.9	32.0	34.2	20.9	26.3	***
Don't know	15.5	15.5	17.5	29.4	17.3	23.9	21.7	***
No testing	21.2	40.3	30.3	13.7	7.2	9.8	12.7	***
All acres	3.1	1.5	11.2	10.2	24.6	49.5	100.0	
Untreated, harvest and po	stharvest ground	water tests pe	r year					
2 or more	2.7	8.6	12.0	20.7	38.4	46.2	32.4	***
1	19.1	56.7	65.5	65.5	45.9	9.4	36.2	***
Someone else tests	0.5	2.4	3.9	1.7	0.5	0.0	0.9	***
Don't know/other	72.7	7.7	8.7	5.7	5.8	38.5	22.4	***
Never	5.1	24.6	9.9	6.4	9.4	6.0	8.1	***
All acres	7.3	3.2	11.1	12.3	31.3	34.8	100.0	

Note: The sample for "Test standard for untreated, preharvest ground or surface water that contacts produce" consists of 1,725 growers covering 515,105 acres. The sample for "Harvest and postharvest untreated ground water tests per year" consists of 754 growers and 173,881 acres. Rows and columns do not necessarily sum to the totals because of rounding.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, ***, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²Other established numerical standards include the Environmental Protection Agency (EPA) recreational water standard, Leafy Green Marketing Agreement standard, maximum of 1,000 *E. coli* CFU/ml, maximum of 500 *E. coli* CFU/ml, reclaimed water standard, or other standards.

Table C-7

Number of tests annually for untreated, preharvest ground or surface water that contacts produce for growers covered by the Produce Rule (PR) by water source

•	-	` ' -		
		Type of water		
	Untreated			Sig.
Tests per year	ground	Untreated surface	All	test ¹
	Pe	ercent of growers within co	lumn	
5 or more	7.0	15.0	9.6	***
1 to 4	63.8	40.9	56.5	***
Someone else tests	3.2	18.9	8.2	***
Never/don't know/other	26.0	25.3	25.7	
All growers	68.1	31.9	100.0	
	F	Percent of acres within colu	umn	
5 or more	15.3	28.0	19.5	***
1 to 4	60.9	50.8	57.5	***
Someone else tests	3.0	6.2	4.1	***
Never/don't know/other	20.9	15.1	19.0	***
All acres	66.6	33.4	100.0	
		· · · · · · · · · · · · · · · · · · ·		

Note: The sample consists of 1,278 growers and 491,638 acres. Rows and columns do not necessarily sum to the totals because of rounding.

^{1&}quot;Sig. test" is a t-test of means for growers who apply ground and surface water as well as for acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

Table C-8
Test standard for preharvest ground or surface water that contacts produce and water treatment for harvest and postharvest water for growers covered by the Produce Rule (PR) by water treatment

	Chemical, UV,				
	filtration, or other	Did a stans st	Do not	A.II	0: 11
	treatment	Did not treat	know	All	Sig. test
-		rcent of growers	witnin column	1	
Test standard for preharvest ground or su		·			*
EPA drinking water	22.4	17.1	10.5	17.4	*
Other established numerical standard2	26.0	16.9	8.1	17.6	***
Normal or within historic range	41.8	27.4	36.0	29.9	***
Don't know	8.7	20.3	38.4	19.8	***
No testing	1.0	18.2	7.0	15.3	***
All growers	13.3	80.9	5.8	100.0	
Harvest and postharvest water source					
Ground	68.9	74.4	26.5	68.0	
Surface	10.5	5.8	7.1	7.1	**
Public potable	19.3	17.6	38.8	20.3	
Other source ³	1.3	2.2	27.6	4.6	***
All growers	24.6	64.9	10.6	100.0	
		Percent of a	cres within co	lumn	
Test standard for preharvest ground or su	rface water that conta	acts produce			
EPA drinking water	7.5	11.3	10.1	10.5	***
Other established numerical standard ²	54.9	30.3	12.7	34.3	***
Normal or within historic range	33.5	25.3	32.8	27.4	***
Don't know	4.1	20.4	41.5	18.3	***
No testing	0.1	12.7	2.9	9.5	***
All acres	20.6	73.1	6.2	100.0	
Harvest and postharvest water source					
Ground	43.3	69.5	11.4	52.1	***
Surface	17.1	5.0	4.5	9.5	***
Public potable	34.5	22.3	46.0	29.9	***
Other source ³	5.1	3.2	38.1	8.5	***
All acres	37.5	49.5	13.0	100.0	

Note: The sample for "Test standard for preharvest ground or surface water that contacts produce" consists of 1,474 growers and 619,541 acres. The sample for "Harvest and postharvest water source" consists of 928 growers and 433,406 acres. UV = ultraviolet light. EPA = Environmental Protection Agency. Rows and columns do not necessarily sum to the totals because of rounding.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²Other established numerical standards include the Environmental Protection Agency recreational water standard, Leafy Green Marketing Agreement standard, maximum of 1,000 *E. coli* CFU/ml, maximum of 500 *E. coli* CFU/ml, reclaimed water standard, or other standards.

³Other water source includes treated waste water, reclaimed tail water, and any other source specified by the respondent.

Table C-9

Manure product use for all growers by size and Produce Rule (PR) coverage

			Covered				_			
Manure product use	Not covered	Qualified exemption	Small	Mid- size	Large	Very large	All	Sig. test ¹		
	Percent of growers within column									
Used untreated manure ²	6.2	5.6	5.3	3.6	2.8	2.2	4.9	***		
Used compost only	7.2	6.9	5.1	7.8	9.2	15.3	7.2			
No manure products	86.7	87.5	89.7	88.6	88.1	82.5	87.9			
All growers	27.1	8.1	35.0	11.4	12.5	5.9	100.0			
			Percent	of acres v	vithin colu	mn				
Used untreated manure ²	1.6	3.7	5.4	3.7	2.1	3.7	3.4	***		
Used compost only	5.2	5.4	3.3	6.6	8.6	21.0	13.3	***		
No manure products	93.2	90.9	91.3	89.7	89.3	75.3	83.3	***		
All acres	9.0	1.1	11.4	8.9	22.6	47.0	100.0			

Note: The sample consists of 4,618 growers and 1,262,604 acres. Rows and columns do not necessarily sum to the totals because of rounding.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table C-10
U.S. Environmental Protection Agency (EPA) time/temperature requirements for growers covered by the Produce Rule using compost by documentation

Meets EPA time/temp requirements	All compost documented	Not fully documented	All	Sig. test ¹
	Percent o	f growers within colum	n	
Yes	87.1	27.7	74.3	***
No	12.9	72.3	25.7	***
All growers	78.4	21.6	100.0	
	Percent	of acres within columr	1	
Yes	93.4	38.6	91.2	***
No	6.6	61.4	8.8	***
All acres	96.1	3.9	100.0	

Note: The sample consists of 218 growers and 161,269 acres.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, ***, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²Growers using untreated manure may also use compost. Untreated manure includes both raw and aged manure.

^{1&}quot;Sig. test" is a t-test of means for growers and acres who documented their composting procedures and those who did not. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

Table C-11

Manure product use for all growers by organic status

Manure product use	No organic acres	Organic acres	All	Sig. test ¹
	Percent of	growers within colu	mn	
No manure products	90.8	50.3	87.9	***
Used compost	4.9	37.5	7.2	***
Used untreated manure	4.3	12.2	4.9	***
All growers	92.9	7.1	100.0	
	Percent o	of acres within colum	nn	
No manure products	92.3	37.0	83.3	***
Used compost	5.7	52.7	13.3	***
Used untreated manure	2.0	10.3	3.4	***
All acres	83.8	16.2	100.0	

Note: The sample consists of 4,618 growers and 1,262,604 acres.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table C-12

Preharvest assessment and monitoring animal intrusion by size and Produce Rule (PR) coverage for all growers

				Cov		_				
	Not covered	Qualified exemption	Small	Mid- size	Large	Very large	All	Sig. test ¹		
	Percent of growers within column									
Preharvest assessment	14.4	22.2	20.6	31.6	40.0	50.8	24.4	***		
Monitor for intrusion	62.0	77.8	65.4	78.1	81.6	81.4	69.9	***		
Intrusion prevention	62.7	84.0	68.0	78.9	83.2	81.4	71.9	***		
All growers	27.1	8.1	35.0	11.4	12.5	5.9	100.0			
		Perce	nt of acre	s within	column					
Preharvest assessment	18.9	18.2	20.2	29.2	43.4	52.1	41.3	***		
Monitor for intrusion	66.7	81.8	57.0	71.9	82.3	72.8	72.6	***		
Intrusion prevention	67.8	81.8	58.8	73.0	81.9	75.7	74.4	***		
All acres	9.0	1.1	11.4	8.9	22.6	47.0	100.0			

Note: The sample consists of 4,618 growers and 1,262,604 acres.

^{1&}quot;Sig. test" is a t-test of means for organic and nonorganic growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

¹"Sig. test" is a t-test of means for organic and nonorganic growers and acres. The null hypothesis is no difference between the means of the two groups. *, ***, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

Table C-13

Animal intrusion prevention by size and Produce Rule (PR) coverage for all growers

			Covered					
Animal intrusion prevention	Not covered	Qualified exemption	Small	Midsize	Large	Very large	All	Sig. test ¹
		Perd	cent of gro	owers within	n column			
Deterrents ²	17.7	39.2	23.4	33.1	36.5	34.3	26.5	***
Fence ³	26.3	32.5	21.9	27.2	35.6	44.5	27.6	
Remove harborage or use buffers ⁴	26.1	41.1	34.7	45.0	48.8	49.6	36.7	***
Trap/shoot	27.7	54.4	36.3	45.1	47.9	43.1	38.3	***
Other methods ⁵	5.4	4.8	5.3	7.2	7.6	8.0	6.0	
All growers	27.1	8.1	35.0	11.4	12.5	5.9	100.0	
		Pe	rcent of a	cres within	column			
Deterrents ²	11.3	40.0	21.5	29.4	33.6	39.9	32.9	***
Fence ³	36.8	27.3	17.1	24.1	33.5	45.4	36.6	***
Remove harborage or use buffers ⁴	21.0	40.4	30.9	41.7	49.8	47.3	43.1	***
Trap/shoot	20.4	60.5	34.1	41.2	44.3	44.1	40.8	***
Other methods ⁵	5.1	3.6	4.3	5.0	6.4	9.3	7.3	***
All acres	9.0	1.1	11.4	8.9	22.6	47.0	100.0	

Note: The sample consists of 4,618 growers and 1,262,604 acres. Growers can report multiple intrusion prevention methods.

1"Sig. test" is a t-test of means for organic and nonorganic growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

²Deterrents include noise makers, gunfire, Mylar strips, fake owls or coyotes, and repellents.

³Fencing put up around fields or around standing surface water.

⁴Harborage includes excess brush, old equipment, and cull piles; buffer zones around a field are intended to increase the ability to detect animal intrusion.

⁵Other methods reported by growers include closely monitoring crops, baiting rodents, encouraging natural predators, using dogs, using bird netting, fencing young fruit trees, and using services of State and national wildlife management agencies.

Table C-14
Cleaning and sanitizing schedule for harvest, field pack, packing house equipment, tools, or bins by size and Produce Rule coverage for all growers

				Cove	ered			
	Not	Qualified				Very	-	Sig.
	covered	exemption	Small	Midsize	Large	large	All	test1
		Perd	ent of gro	wers within o	column			
Cleaning schedule								
Daily	54.4	60.1	60.5	59.2	64.2	67.7	60.0	***
Weekly	16.9	16.8	15.1	21.3	19.1	20.5	17.4	
Monthly	4.0	3.6	2.8	2.9	3.7	4.1	3.4	
Seasonally	13.3	9.0	12.6	10.9	7.7	4.1	10.9	
NA/Other	7.0	7.2	6.9	5.0	4.1	3.2	6.1	**
Never	4.4	3.3	2.0	0.7	1.2	0.5	2.3	***
All growers	22.3	9.9	33.3	13.0	15.1	6.5	100.0	
Sanitizing schedule								
Daily	33.8	39.9	43.3	44.4	51.5	57.3	43.1	***
Weekly	13.8	17.2	14.4	19.8	16.7	14.5	15.6	
Monthly	5.2	4.5	4.7	5.0	8.1	8.6	5.6	
Seasonally	15.2	13.6	15.6	12.3	11.0	9.1	13.8	
NA/Other	12.6	8.8	9.5	8.9	6.7	6.4	9.4	***
Never	19.4	16.0	12.5	9.6	6.1	4.1	12.5	***
All growers	22.2	9.8	33.3	13.0	15.1	6.5	100.0	
		Pe	rcent of ac	res within co	olumn			
Cleaning schedule								
Daily	48.1	65.7	62.6	57.3	58.0	59.9	58.5	***
Weekly	39.1	16.0	16.3	24.2	25.8	26.4	26.2	***
Monthly	2.4	3.0	2.5	3.7	4.1	7.1	5.1	***
Seasonally	4.1	7.1	10.0	9.5	6.3	5.2	6.2	***
NA/Other	5.8	5.8	6.6	4.8	4.4	1.2	3.3	***
Never	0.6	2.4	2.0	0.4	1.4	0.2	0.7	**
All acres	9.1	1.3	9.2	8.8	25.5	46.2	100.0	
Sanitizing schedule								
Daily	23.1	42.1	41.0	43.1	46.2	50.8	45.4	***
Weekly	18.2	17.5	15.5	21.1	20.4	20.0	19.6	***
Monthly	25.8	3.8	4.2	5.7	9.6	4.8	7.9	***
Seasonally	20.6	11.6	13.7	13.4	9.8	13.8	13.3	***
NA/Other	6.5	9.2	10.2	8.3	6.5	3.7	5.7	***
Never	5.9	15.7	15.4	8.3	7.5	7.0	8.0	***
All acres	9.1	1.3	9.1	8.7	25.5	46.3	100.0	

NA = not applicable

Note: The sample for "cleaning schedule" consists of 3,380 growers covering 964,175 acres who use harvest or field packing tools, harvest or field packing machinery, packing house tools, postharvest machinery and work surfaces, harvest bins, and transportation bins. The table shows respondents' most frequent-reported cleaning of multiple items. The sample for "sanitizing schedule" consists of 3,368 growers covering 962,628 acres who use harvest or field packing tools, harvest or field packing machinery, packing house tools, postharvest machinery and work surfaces, harvest bins, and transportation bins. The figure shows respondents' most frequent-reported cleaning among multiple items. Rows and columns do not necessarily sum to the totals because of rounding.

1"Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

Table C-15

Number of harvest workers per toilet and sink pairs by size and Produce Rule (PR) coverage among growers with harvest workers

				Covered				
	Not covered	Qualified exemption	Small	Midsize	Large	Very large	All	Sig. tes ^{t1}
		Pe	ercent of gr	owers within	column			
1 to 10	49.8	57.6	51.5	39.8	36.2	35.0	47.1	***
11 or more	18.1	28.7	31.5	51.2	59.5	59.4	36.0	***
No toilet or sink	32.1	13.8	17.0	8.1	4.3	5.6	16.9	***
All growers	24.9	9.1	33.8	12.4	13.8	6.0	100.0	
		I	Percent of a	acres within d	column			
1 to 10	31.9	57.1	49.1	36.4	33.9	34.1	35.9	***
11 or more	58.8	33.0	28.3	52.2	59.4	57.4	54.3	***
No toilet or sink	9.3	9.9	22.5	11.4	6.7	8.5	9.8	***
All acres	9.3	1.3	9.9	9.3	25.3	44.8	100.0	

Note: The sample consists of 3,897 growers and 1,031,010 acres. For 10 growers who report having sinks and toilets but do not report the number, we assume they have 1 of each. For 36 growers who report having harvest workers but do not report the number, we assume they have more than 10 harvest workers per toilet and sink. Rows and columns do not necessarily sum to the totals because of rounding.

^{1&}quot;Sig. test" is a t-test of means for growers and acres not covered by the PR (including growers with a qualified exemption for the purpose of this test) and for covered growers and acres. The null hypothesis is no difference between the means of the two groups. *, **, and *** indicate rejection of the null hypotheses (i.e., the means are statistically different) at the 10-, 5-, and 1-percent confidence levels, respectively.

Appendix D – Imputation Robustness Checks

Table D-1

Difference in State percentage of total, omitting imputed size and Produce Rule coverage growers

State	Imputed	Omitted	Difference
AZ	0.24	0.25	0.01
CA	27.35	27.25	0.10
FL	3.53	3.19	0.34
GA	3.05	2.99	0.06
IL	1.26	1.30	0.04
IN	1.04	1.07	0.03
MI	10.81	11.08	0.27
MN	5.00	5.05	0.05
NC	4.40	4.40	0.00
NJ	3.42	3.48	0.06
NY	6.15	6.23	0.08
ОН	3.62	3.73	0.11
OR	7.56	7.37	0.19
PA	5.05	5.20	0.15
SC	1.28	1.23	0.05
TN	0.65	0.65	0.00
TX	5.37	5.45	0.08
WA	7.41	7.30	0.11
WI	2.84	2.77	0.07
N	4,618	4,477	141

N = number of respondents.

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics. The percentage of the sample located in each State differs by a maximum of 0.34 percentage points.

Table D-2

Difference in crop percentage of total, omitting imputed size and Produce Rule coverage growers

Crop	Imputed	Omitted	Difference
All other fruits and vegetables	1.63	1.67	0.04
Apples/pears	9.85	9.87	0.02
Berries	7.73	7.70	0.03
Brassicas	1.63	1.67	0.04
Citrus	7.67	7.57	0.10
Cucumbers	2.55	2.60	0.05
Grapes	4.62	4.48	0.14
Green beans/peas	5.30	5.22	0.08
Herbs	0.65	0.66	0.01
Leafy greens	3.90	3.95	0.05
Melons	4.22	4.23	0.01
Nuts	2.37	2.29	0.08
Peppers	2.58	2.64	0.06
Pulses	0.28	0.26	0.02
Root crops	3.42	3.36	0.06
Squash/pumpkins	8.95	9.13	0.18
Stone fruit	14.76	14.73	0.03
Sweet corn	8.77	8.80	0.03
Tomatoes	5.37	5.48	0.11
Tropical/Mediterranean	3.75	3.68	0.07
N	10,333	10,022	311

N = number of respondents.

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics. The percentage of the sample growing commodity groups differs by a maximum of 0.18 percentage points.

Table D-3

Difference in crop acreage percentage of total, omitting imputed size and Produce Rule coverage growers

Crop	Imputed	Omitted	Difference
All other fruits and vegetables	1.35	1.42	0.07
Apples/pears	8.58	9.01	0.43
Berries	3.93	4.07	0.14
Brassicas	2.64	2.83	0.19
Citrus	10.68	10.67	0.01
Cucumbers	1.48	1.58	0.10
Grapes	11.77	11.24	0.53
Green beans/peas	6.74	6.27	0.47
Herbs	0.74	0.79	0.05
Leafy greens	10.36	11.08	0.72
Melons	2.38	2.38	0.00
Nuts	6.96	7.27	0.31
Peppers	0.69	0.73	0.04
Pulses	0.34	0.34	0.00
Root crops	4.43	3.60	0.83
Squash/pumpkins	1.84	1.94	0.10
Stone fruit	8.69	9.01	0.32
Sweet corn	7.16	6.47	0.69
Tomatoes	6.53	6.93	0.40
Tropical/Mediterranean	2.73	2.35	0.38
N	1,198,860	1,117,937	80,923

N = number of respondents.

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics.

The percentage of the acres in commodity groups differs by a maximum of 0.83 percentage points.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table D-4

Difference in 3-year average annual gross value of produce sales, percentage of total, omitting imputed size and Produce Rule coverage growers

Sales	Imputed	Omitted	Difference
Less than \$25,000	18.23	18.20	0.03
\$25,000 to less than \$500,000	49.72	50.39	0.67
\$500,000 to less than \$1 million	12.15	11.77	0.38
\$1 million to less than \$5 million	13.56	13.49	0.07
\$5 million or more	6.34	6.14	0.20
N	4,618	4,477	141

N = number of respondents.

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics. The percentage of the sample within sales categories differs by a maximum of 0.67 percentage points.

Table D-5

Difference in produce acres grown, percentage of total, omitting imputed size and Produce Rule coverage growers

Acres grown	Imputed	Omitted	Difference
0 to 9 acres	15.20	15.39	0.19
10 to 99 acres	44.48	44.94	0.46
100 to 999 acres	35.23	34.76	0.47
1,000 acres or more	5.09	4.91	0.18
N	4,618	4,477	141

N = number of respondents

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics. The percentage of sample within produce acres grown categories differs by a maximum of 0.47 percentage points.

Source: USDA, Economic Research Service's and USDA, National Agricultural Statistics Service's (NASS)—jointly conducted—Produce Grower Food Safety Practices Surveys 2015 and 2016.

Table D-6

Difference in size and Produce Rule coverage categories, percentage of total omitting imputed size and Produce Rule coverage growers

Size and Produce Rule coverage	Imputed	Omitted	Difference
Exempt	27.11	27.36	0.25
Qualified exemption	8.13	8.27	0.14
Small covered	34.98	35.30	0.32
Midsize covered	11.38	10.98	0.40
Large covered	12.48	12.39	0.09
Very large covered	5.92	5.70	0.22
N	4,618	4,477	141

N = number of respondents

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics. The percentage of sample within size and Produce Rule coverage category differs by a maximum of 0.40 percentage points.

Table D-7

Difference in percentage of total who were aware of Produce Rule (PR), omitting imputed size and Produce Rule coverage growers

Heard of PR	Imputed	Omitted	Difference
Have heard of PR	59.19	59.49	0.30
Have not	40.81	40.51	0.30
N	4,618	4,477	141

N = number of respondents.

Note: Omitting the 141 observations that we impute does not substantively change the sample characteristics. The percentage of sample that has heard of FSMA PR differs by a maximum of 0.30 percentage points.