



United States Department of Agriculture

Economic  
Research  
Service

Economic  
Information  
Bulletin  
Number 210

June 2019

# U.S. Produce Growers' Decisionmaking Under Evolving Food Safety Standards

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United States Department of Agriculture

## Economic Research Service [www.ers.usda.gov](http://www.ers.usda.gov)

### **Recommended citation format for this publication:**

Astill, Gregory, Travis Minor, Suzanne Thornsby, and Linda Calvin. *U.S. Produce Growers' Decisionmaking Under Evolving Food Safety Standards*, EIB-210, U.S. Department of Agriculture, Economic Research Service, June 2019.

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## **Abstract**

U.S. produce growers have faced increased demand for implementing additional food safety practices, prompted by a series of high-profile foodborne illness outbreaks. This report summarizes a series of open-ended discussions with produce growers and reveals the nuanced reasoning behind growers' actions in response to evolving food safety standards in a complex market. Growers of five commodities in six regions reveal the long history of food safety standards in the industry, including voluntarily implemented standards developed by themselves, commodity organizations, and government agencies as well as those required by some commercial buyers and some States. Growers most confident in their ability to adapt to new food safety regulations—like the “Produce Rule” in the Federal 2011 Food Safety Modernization Act—had two key characteristics in common: a background and culture of food safety at their company and a well-developed food safety information network. Growers agreed that the adoption of food safety standards have been driven largely by commercial buyer requirements. Highly competitive markets force growers to weigh the hard-to-quantify benefits of risk-reducing practices against their significant costs.

**Keywords:** food safety, microbial contamination, produce, produce growers, Produce Rule, case study

## **Acknowledgments**

The authors would like to thank the many produce growers who spoke at length about their operations. The authors thank the representatives from grower organizations, agricultural Extension, and State departments of agriculture who facilitated open-ended communications with produce growers. The authors thank the following individuals for technical peer reviews: Linda Abbott, USDA, Office of the Chief Economist; Samir Assar, Food and Drug Administration; Helen Jensen, Iowa State University; and one reviewer who requested anonymity. Thanks also to Dale Simms and Cynthia A. Ray, USDA, ERS, for editorial and design services.

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# U.S. Produce Growers' Decisionmaking Under Evolving Food Safety Standards

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## What Is the Issue?

U.S. produce growers have faced increased demand for implementing food safety practices, prompted by a series of high-profile foodborne illness outbreaks. Most recently, the “Produce Rule” (PR)—mandated by the Food Safety Modernization Act (FSMA) of 2011—presents a new set of federally mandated standards for produce growers. Little information exists about how and why produce growers decide to implement various food safety practices. This report addresses that information gap, summarizing a series of open-ended discussions with produce growers, trade organization representatives, and others that indicate the nuanced reasoning behind growers' actions in response to evolving food safety standards.

## What Did the Study Find?

The U.S. produce industry is highly diverse in terms of fruits and vegetables (and other specialty crops) grown, the marketing channels sold to, and the characteristics of operations. Like the U.S. farm sector as a whole, most produce operations are very small or small farms (less than \$500,000 in annual sales), but collectively they make up only a small percentage of the total U.S. value of produce production. This case study focused on six produce regions that varied in climatic, economic, and agricultural characteristics—the Northwest, central California, the Southwest, the Lake States, the Northeast, and the Southeast—and on five commodities with diverse contamination risks, harvest methods, perishability, and means of consumption—apples, cantaloupe, strawberries, onions, and tomatoes. Most growers who grew one of the five crops also grew others.

**Commonalities in case study growers' approach to food safety were stronger than differences across the produce industry.** With surprisingly few exceptions, growers' approach to food safety in different commodity sectors and different regions is very similar. The main differences arose between small growers and medium or large growers and between growers marketing directly to consumers, restaurants, or retailers and growers selling to other marketing channels.

**Produce growers in the case study described their long history of adapting to changing food safety requirements.** Growers most confident in their ability to adapt to new food safety standards shared two key characteristics: a background and culture of food safety at their company and a well-developed food safety information network.

**These produce growers reported that retail and foodservice buyer requirements have largely driven the adoption of food safety practices.** Growers in the case study noted strong commercial incentives to adopt food safety practices to protect consumers and maintain

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relationships with major buyers/retailers. Some growers reported tension with buyers/retailers over the assignment of liability, demands for new practices and facilities, and extensive third-party audits.

**Collaboration with private and public sector partners opens food safety communication channels.**

Many produce growers in the case study attributed their success in implementing a food safety program to the support they received through their contract partnerships with other growers. Also, these growers said advice from regional commodity organizations, State departments of agriculture, and agricultural extension helped them implement food safety standards, including the PR.

**Growers operating in a highly competitive market weigh the hard-to-quantify benefits of risk-reducing practices against their significant costs.** Reported food safety costs included hiring staff and consultants, training supervisors and employees, developing a system of recordkeeping, and replacing inadequate buildings and equipment. Although growers frequently cited water testing as a challenge, earlier ERS studies indicated that water testing costs are the least of any measured food safety practice.

**Case study growers at every stage of adoption of formal food safety practices voiced uncertainty over some PR requirements.** At the time of the case study, the U.S. Food and Drug Administration was still drafting guidance on PR standards and official training was ramping up. Both growers and those who advise them were uncertain about water standards and whether additional rules for food facilities would apply to their operations.

**Participating growers cited additional challenges such as multiple layers of State and Federal regulations, numerous audits, and capacity constraints for food safety services.** The growers emphasized that food safety is only one of many attributes that make a produce company viable in the modern market and repeatedly brought up “audit fatigue.” Also, these growers saw the limited supply of professionals with specialized technical knowledge of food safety to be a constraint for growers and auditors.

**Growers in the case study described how seasonality, geographical dispersion, and perishability of produce crops contribute to a highly dynamic and complex produce market that is especially challenging for small growers.** The diverse types of growers, buyers, and retailers implement safe practices to protect consumers and shield themselves from potential liability due to foodborne illness. Growers of all sizes in the case study questioned whether smaller farms would be excluded from supply chains under new food safety standards due to the cost of hiring a food safety supervisor or replacing inadequate buildings and equipment.

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

ERS researchers conducted six field trips between 2016 and 2017 to meet with groups of one to three produce growers, food safety supervisors, officials from State departments of agriculture, agricultural extension personnel, or trade organization representatives. About 50 individuals participated in the meetings. Through in-depth conversations, ERS researchers explored the nuances of grower decisionmaking surrounding food safety practices and discovered growers’ most pressing concerns. Discussions were free-form, generally starting on the topic of food safety, but moved to many different aspects of the growing operation.

ERS spoke with growers with operations of widely varying sizes, marketing arrangements, and business structures; and growers representing different demographic characteristics, experiences, and backgrounds. ERS talked with growers who would be covered by the PR, as well as others who would not be covered or would qualify for an exemption. In a few cases, follow-up conversations occurred over the phone. Qualitative results in this report expand upon work published in two related ERS reports on the food safety practices of produce growers: a 2015-16 survey of U.S. produce growers (Astill et al., 2018) and a 2016-17 case study of produce retailers (Minor et al., 2019).

# U.S. Produce Growers' Decisionmaking Under Evolving Food Safety Standards

## Background

About 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 cause an estimated annual burden of \$14 billion (Hoffmann et al., 2012) to \$36 billion (Minor et al., 2015). Produce has been implicated in 46 percent of foodborne illnesses outbreaks (Painter et al., 2013). In the first half of 2018, the U.S. Food and Drug Administration (FDA) reported 300 illnesses and 5 deaths linked to outbreaks in melons and romaine lettuce (2018a, 2018b).

Microbial food safety in produce became a prominent issue in the mid-1990s following several outbreaks involving both domestic and imported produce (Calvin, 2003). Additional outbreaks increased support for Federal regulation (Stenzel, 2009). Federal development of onfarm food safety standards began with voluntary frameworks. The FDA developed voluntary produce food safety guidelines, known as Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), starting in 1998 (FDA, 1998). In 2002, USDA's Agricultural Marketing Service (AMS) formally implemented the GAP and Good Handling Practices (GHP) audit verification program (USDA AMS, 2018a).

Concurrent with the development of voluntary Federal food safety standards, various third-party organizations (PrimusGFS, SQF, GlobalGAP, etc.) began offering audit services using their own developed standards. Commercial buyers could request that an audit cover additional factors (for example, increasing the area of crop surrounding observed animal contamination to not be harvested or including an additional washing step after harvest) and developed audit riders to augment third-party standards. In response to the number of international, independent food safety audit standards, food companies developed the Global Food Safety Initiative (GFSI) in 2000, which benchmarked audit standards to determine equivalency (GFSI, 2017). Walmart adopted mandatory GFSI-benchmarked audits for its produce suppliers in 2008 (Suarez, 2008). By 2009, other grocers like Ahold, Delhaize, H-E-B, Kroger, Wegmans, and ShopRite began accepting GFSI-benchmarked audits as well (Garren, 2009).

Alongside the development of these voluntary Federal and third-party standards, regional and commodity-specific grower associations developed their own standards specific to their markets. After large foodborne illness outbreaks in 2006 linked to spinach and lettuce, Californian leafy green growers coordinated to establish the Leafy Green Marketing Agreement in 2007 (Calvin, 2007). Tomatoes were implicated in foodborne illness outbreaks every few years from 1998 to 2006 (Guzewich, 2006; Olaimat and Holley, 2012). Through the Florida Tomato Committee, tomato growers backed a State law regulating the safe production and handling of all commercially sold tomatoes in 2008 (Florida Tomato Committee, 2018).<sup>1</sup> (See box, "Tomato Background.")

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<sup>1</sup>The same year that Florida tomato growers adopted mandatory GAPs, the FDA issued a warning incorrectly tracing a *salmonellosis* outbreak to Florida tomatoes. The FDA later concluded the outbreak was caused by jalapeño and serrano peppers grown in Mexico (FDA, 2009). The Florida Tomato Committee (2008) estimated that the sharp drop in demand after the FDA warning caused Florida tomato growers and packers to lose \$100 million in revenue.

After two, large multistate outbreaks involving cantaloupe (Olaimat and Holley, 2012; Fischer et al., 2015), growers in each implicated production region banded together to create voluntary regional commodity associations with mandatory food safety standards—the Rocky Ford Growers Association in Colorado in 2011 and the Eastern Cantaloupe Growers Association in 2012. The California Cantaloupe Advisory Board (CCAB), established in 1988, implemented mandatory food safety standards for the State’s cantaloupe growers and packers in 2012 (CCAB, 2018).

By 2011, various voluntary Federal, third-party, and grower association standards existed to prevent the contamination of produce, but Federal law addressing food safety had been largely unchanged since the Federal Food, Drug, and Cosmetic Act of 1938. The Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, is the most significant change to U.S. food safety laws in over 70 years. FSMA establishes a national approach to regulating food safety, shifting the policy focus from reaction (to foodborne-illness outbreaks) to risk-based preventive action.

FSMA standards address many of the same potential risks as addressed by the standards of third-party food safety audits. In 2015, under the FSMA umbrella, FDA released two rules that most directly impact U.S. produce growers:

- the “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food,” known as the “Preventive Controls Rule,” or PC Rule and
- the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” known as the “Produce Rule” (PR).

The PR (referred to by FDA as the “Produce Safety Rule”) represents the first onfarm FDA regulation for U.S. produce and sets specific food safety practice standards to reduce the risk of microbial contamination. Most PR standards became mandatory in January 2018 for produce growers with more than \$500,000 in sales, with later compliance dates and other standards for smaller growers. Summaries of some standards in the PR can be found in the companion survey results report (Astill et al., 2018). Readers should refer to the published PR (FDA, 2015a), PC Rule (FDA, 2015b), and FDA guidance (FDA, 2018c; FDA, 2018d) for official language and interpretation.

The PR does not cover the 61.9 percent of U.S. produce growers who sell less than \$25,000 in produce annually (FDA, 2015c). However, these very small growers are still subject to the food safety standards required by buyers in the marketing channels they sell to. A small share of U.S. produce growers are large, but these large growers supply a disproportionate share of produce to the market. According to the 2012 Census of Agriculture, less than 1 percent of fruit and vegetable growers made up the top 25 percent of value of produce production and less than 10 percent made up the top 75 percent (NASS, 2014).



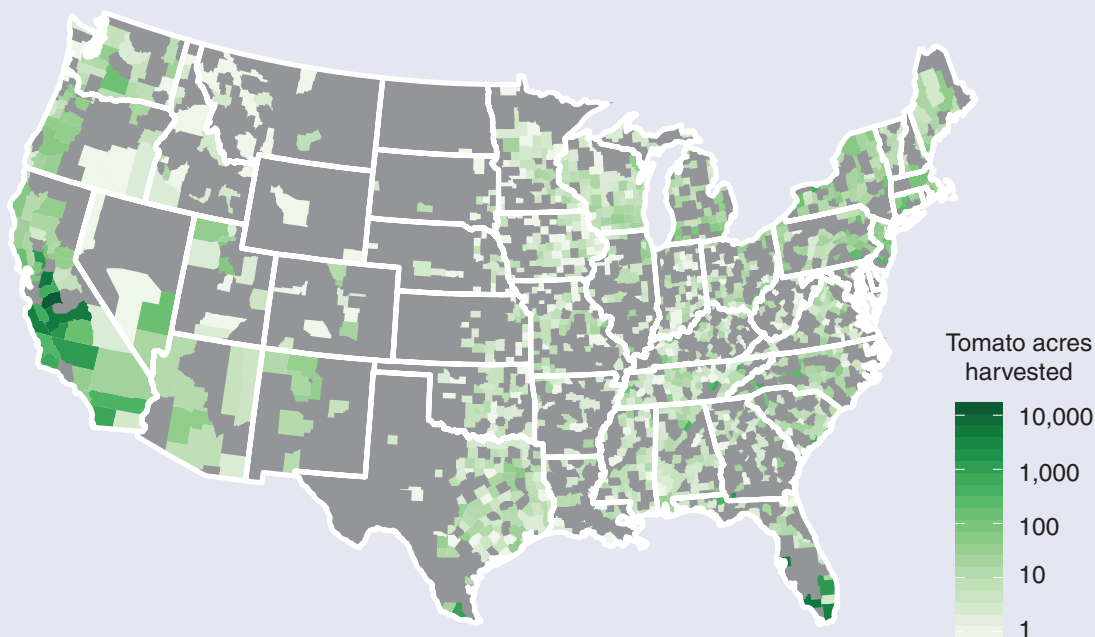
## Tomato Background

Tomatoes are botanically a fruit, but they are most commonly used in cuisine like a vegetable and are legally classified as such. Most tomatoes for the fresh market grow on bushy plants off the ground in fields. Increasingly, tomatoes are grown on long vines suspended in greenhouses (although greenhouse tomatoes are not covered in this report). In 2012, California harvested about half of all U.S. fresh tomato acres, and Florida harvested about a fifth (box fig. 1.1). Per capita availability of fresh tomatoes increased from 19 pounds in 2000 to 20.5 pounds in 2015 (Parr et al., 2018a). Fresh tomato imports increased from 30 percent of fresh tomatoes available in 2000 to 60 percent in 2016. Exports have remained fairly level, averaging 8 percent of production since 2000. Imports of fresh tomatoes are generally higher in the spring than in the fall (Parr et al., 2018b).

Tomatoes have been implicated in a number of foodborne illness outbreaks since 1998 (box fig. 1.2). Ten outbreaks have caused more than 100 illnesses, while 2 were associated with deaths of individuals. The most prominent recent case in 2015 involving Chipotle sickened 119 individuals with *E. coli* O26 and hospitalized 17. Although the FDA never identified a single field or source of contamination, Chipotle was reported to have traced the contaminated tomatoes back to a farm in Virginia (Minnesota Department of Health, 2015). In 2005 and 2006, multiple multistate outbreaks of *salmonella* in tomatoes sickened 487 individuals. In separate cases, contamination was traced back to irrigation pond water on Virginia farms; animal feces, farm surfaces, and ditch water on a Florida farm; and unknown sources on three farms in Ohio (Centers for Disease Control and Prevention, 2007).

Box figure 1.1

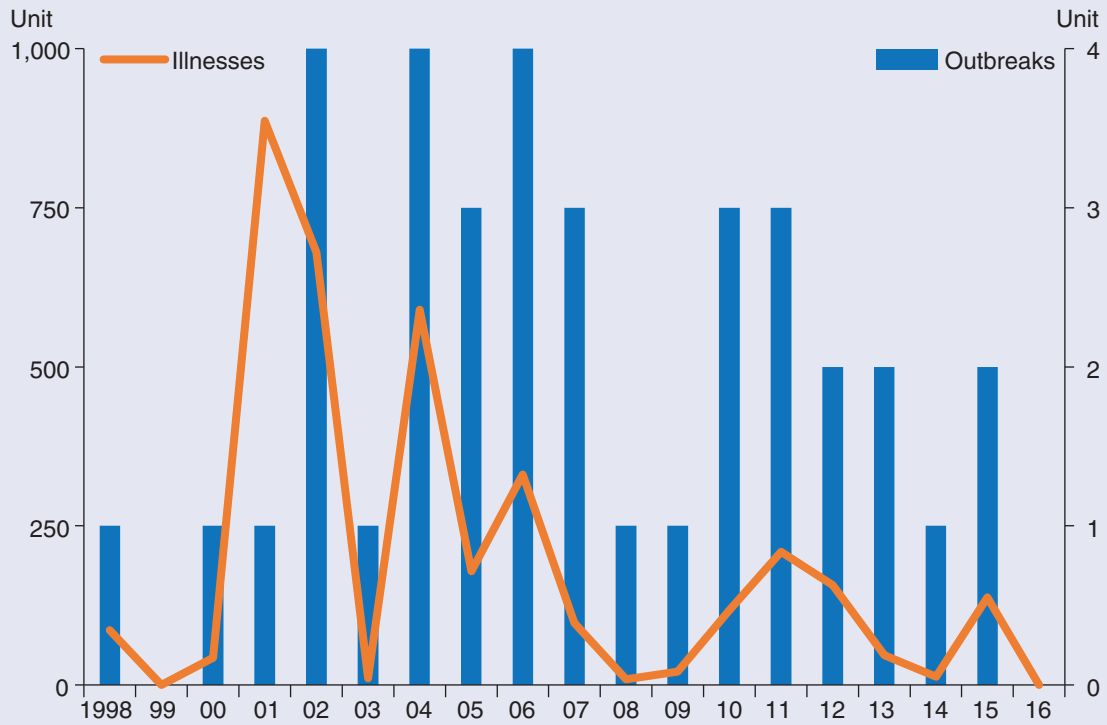
**Tomato (field, fresh-market) acres harvested by county**



Source: USDA, National Agricultural Statistics Service (2015), 2012 Census of Agriculture.

Box figure 1.2

### Illnesses and outbreaks associated with fresh tomatoes, 1998-2016



Note: Includes outbreaks for which tomato is the sole contaminated ingredient, or if not, the sole food vehicle. Excludes cases of norovirus.

Source: U.S. Centers for Disease Control and Prevention, 2017.

## Case Study Discussions

ERS has investigated the food safety-related challenges produce growers face using a combination of statistical surveys and open-ended discussions. One study reported results of the ERS/NASS 2015-16 Produce Grower Food Safety Practices Surveys to assess the adoption of food safety practices (Astill et al., 2018). Another study summarized a series of open-ended discussions with produce buyers who represent food retail companies (Minor et al., 2019). The current study reports a parallel set of discussions with produce growers and other personnel engaged in onfarm food safety work to provide additional insights about the challenges facing growers in a changing regulatory environment.

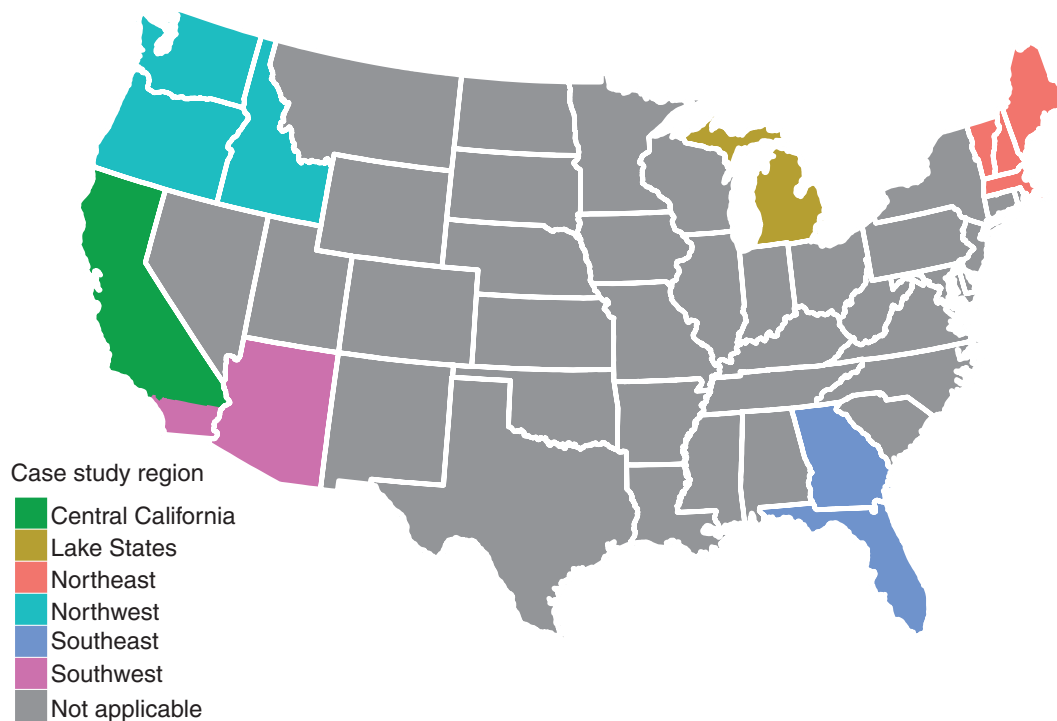
A case study is best suited to answer “how” or “why” questions in situations characterized by complex interactions among multiple entities (Yin, 2009). Case studies, rather than establishing a statistically valid description of the grower population of interest, provide a limited set of detailed and complex descriptions of the factors that contributed to food safety decisions in the grower population. The detailed descriptions of the reasoning behind grower food safety decisions summarized in this report complement the statistically rigorous summaries of food safety practices reported by Astill et al. (2018) and the views of produce buyers reported by Minor et al. (2019).

During 2016 and 2017, teams of ERS economists traveled to six produce growing regions where discussions with produce growers were arranged by local contacts or directly with growers. The team met with the farm’s owner/operator and a specialized food safety supervisor when one was employed by the farm. In some cases, officials from State departments of agriculture, agricultural extension personnel, and trade organization representatives were present for the discussions and provided their perspectives, but the discussion centered on the issues facing produce growers and is framed as such in this report.

Discussions were free-form. Discussions generally started on the topic of food safety, but later moved to many different aspects of the growing operation. Open-ended conversations allowed researchers to identify knowledge gaps, nuances in growers’ decisionmaking, and growers’ complex concerns. In a few cases, follow-up conversations occurred over the phone.

Discussions focused on five commodities—apples, cantaloupe, strawberries, onions, and tomatoes. Most growers who grew one of the five crops also grew others. The regions varied in their climatic, economic, and agricultural characteristics: the Northwest (Idaho, Oregon, and Washington), Central California (excluding the four southern-most counties), the Southwest (Arizona and the four southern-most counties in California), the Lake States (Michigan), the Northeast (Maine, Massachusetts, New Hampshire, and Vermont), and the Southeast (Georgia and Florida) (fig. 1).

Figure 1  
**Case study regions**



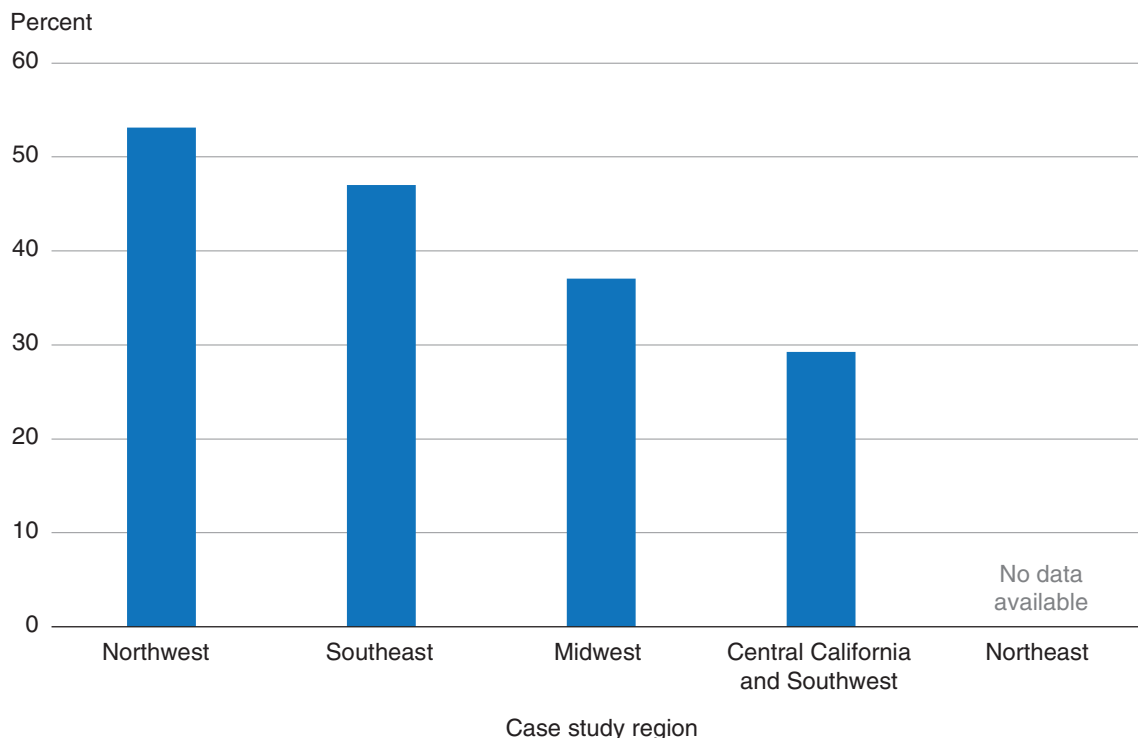
Source: USDA, Economic Research Service.

These regions capture the wide variability in growing conditions across the United States. For example, in many parts of the West produce growers require irrigation, while produce growers in many parts of the East irrigate only during dry years or not at all. Temperatures in the Southwest and Southeast can support nearly year-round production, except for a few weeks in the summer when temperatures are too high. The length of the growing season is shorter farther North, with the main growing season occurring during summer. These regions exhibited differences in the percentage of growers who had third-party audits; the Northwest had the most and central California and the Southwest had the least (fig. 2).



Figure 2

**Percentage of growers with food safety audits within case study regions, 2015-16**



Note: 2,426 growers; because survey data only identified the States where growers were located, not counties, the central California and Southwest regions are combined to be growers from California and Arizona. The States in the Northeast region of the case study—Maine, Massachusetts, New Hampshire, and Vermont—were not surveyed.

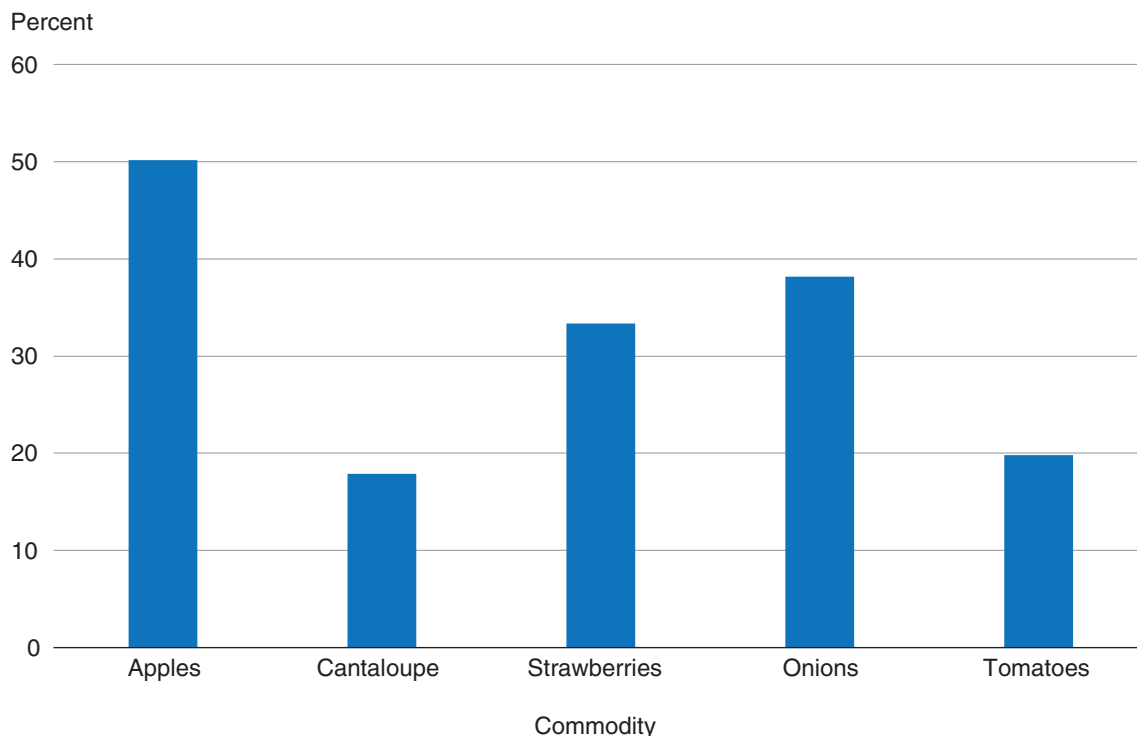
Sources: USDA, Economic Research Service/National Agricultural Statistics Service, 2015-16 Produce Grower Food Safety Practices Surveys.

The five produce commodities included represent a range of produce, labor, and mechanical intensity. Differing characteristics influence vulnerability to food safety risks, including proximity to the ground; harvest methods; perishability; and ways of consumption. Apples (see box, “Apple Background”), cantaloupe (see box, “Cantaloupe Background”), and strawberries (see box, “Strawberry Background”) are fruit crops, and onions (see box, “Onion Background”) and tomatoes (see box, “Tomato Background”) are vegetable crops.<sup>2</sup> One goal of this study was to maximize coverage of the different growing and harvesting styles across produce commodities. An indicator of the varying stringency of food safety requirements is the percentage of growers who underwent third-party food safety audits: about half of apple growers were audited versus less than 20 percent of cantaloupe growers (fig. 3).

<sup>2</sup>Tomatoes are botanically classified as a fruit, but legally and culinarily classified as a vegetable.

Figure 3

**Percentage of growers with food safety audits by commodity, 2015-16**



Note: 1,741 growers; some growers may be double-counted if they grew multiple commodities

Sources: USDA, Economic Research Service/National Agricultural Statistics Service, 2015-16 Produce Grower Food Safety Practices Surveys.

Washington contains 51 percent of U.S. *apple* bearing acres, Michigan 10 percent, California 4 percent, and Massachusetts and Vermont 1 percent each. California is home to 51 percent of *cantaloupe* acres, Arizona 27 percent, Georgia 6 percent, and Florida 4 percent. California grows 72 percent of *strawberry* acres, Florida 20 percent, Oregon 3 percent, and Washington 2 percent. California produces 35 percent of dry *onion* acres, Washington 18 percent, Oregon 14 percent, Georgia 8 percent, and Idaho 7 percent. Finally, California grows 48 percent of fresh-market *tomato* acres in field production, and Florida grows 21 percent.<sup>3</sup>

Although this case study focused on producers of apples, cantaloupe, strawberries, onions, and tomatoes, many of the growers in the case study grew multiple produce commodities. ERS spoke with growers with operations of widely varying sizes, marketing arrangements, and business structures; and growers representing different demographic characteristics, experiences, and backgrounds. ERS spoke with growers who would be covered by the Produce Rule, as well as others who would not be covered or would qualify for an exemption.

The person (or people) in the organization participating in discussions had the most direct responsibility for food safety decisions. For smaller operations, the owner/grower was often responsible for food safety along with most or all other facets of production. In larger operations, there was often a food safety supervisor who worked under the direction of the owner/grower. In all such

<sup>3</sup>Greenhouse tomatoes are not covered in this report.

operations, the food safety supervisor worked closely with and frequently communicated with the owner/grower regarding how food safety policies and practices were carried out on the operation. Throughout the rest of this report, the term “grower” is used to refer both to an owner-grower who is the main food safety supervisor and an owner-grower/food safety supervisor pair who work jointly to manage food safety.

## Major Themes Identified in This Study

This report provides insight into the motivations, concerns, and objectives of produce growers when they perform food safety activities. Discussions with growers were broadly consistent with other studies on growers' food safety practices (Minor et al., 2019; Adalja and Lichtenberg, 2018; Astill et al., 2018; Calvin et al., 2017; Lichtenberg and Tselepidakis Page, 2016; Marine et al., 2016; Sullins, 2014; Prenguber and Gilroy, 2013; Becot et al., 2012; Hultberg et al., 2012; Hardesty and Kusunose, 2009; Rangarajan et al., 2002). For example, growers emphasized their long history of complying with food safety requirements and the role of buyers in driving adoption of these requirements. These assessments corroborate an ERS case study in which nine retail buyers said they have required food safety audits for years and they avoid buying from growers who forgo audits (Minor et al., 2019). Concerns about the ability of small growers to adopt food safety practices are consistent with survey findings of low adoption rates by small growers (Astill et al., 2018).

Open-ended discussions revealed more concrete concerns, such as tensions between growers and retailers over liability for a food safety outbreak, the inability of small growers to hire specialized food safety supervisors, and requirements for packing sheds. On the other hand, growers frequently expressed concerns about water regulations and testing that seemed inconsistent with survey and case study results that reveal the relatively low costs of water-related compliance (Astill et al., 2018; Calvin et al., 2017).

While the recently implemented Produce Rule (PR) marks a significant change to Federal law impacting produce growers, it is not the only change to food safety standards for produce in recent years. Growers, commodity organizations, commercial buyers, and government agencies have long implemented changes to food safety standards. The growers associated with the six regions and five commodities in this case study exhibit more similarities than differences in food safety standards and practices.

Across all commodities and regions, *growers who have developed a culture of food safety were closely connected to the commercial networks that have driven third-party food safety standards.* All growers supported growing safe food, but food safety practices used by growers vary widely. Retail and foodservice buyers have largely driven the adoption of food safety practices among U.S. produce growers who sell to them. In some cases, regional commodity organizations facilitate access to large buyers for members by establishing mandatory food safety standards enforced by third-party audits. A complementary driving force behind adoption is company leadership who prioritize food safety. Many growers already met or exceeded Produce Rule standards while others fell short. Some growers thought the PR formalized what was already in wide use, and some viewed it as a “floor” to bring all growers up to a minimum standard.

Second, growers at every stage of adoption of formal food safety practices repeatedly discussed *uncertainty about what the PR requires, how PR standards fit with private standards, and more generally how liability is transferred in a complex supply chain.* For example, PR water standards have been delayed and manure application standards have yet to be drafted. Even individuals tasked with advising members of the produce industry on PR standards expressed uncertainty about how certain rules would be interpreted. Exemptions for small growers allow for the unique arrangements surrounding marketing directly to consumers, restaurants, or retailers, but it is uncertain whether growers would restructure their businesses to claim these exemptions. Members of the produce industry consistently expressed the desire for clear guidance from the FDA on PR implementation.



Some growers were taking a wait-and-see approach before making costly investments to comply, as undertaking unnecessary changes may unduly raise startup costs related to the PR.

Third, common to growers at all stages of implementing food safety practices were *challenges upon first implementing a formal food safety program*, regardless of federally mandated rules. Growers reported that startup costs—hiring staff and/or consultants, training supervisors and employees, developing a system of recordkeeping, and replacing inadequate buildings and equipment—were significant. Maintaining formal food safety practices was reported to be costly and included regular employee training, microbial testing of water and product, audits, prevention of animal intrusion, and recordkeeping. Some growers lamented that excessive and ever-changing food safety standards and intensive recordkeeping distract from their core business of growing produce; still, many were willing to make investments that they believed reduced food safety risks and satisfied buyers' requirements.

## Development of a Culture of Food Safety

Verifying the effectiveness of specific food safety practices is difficult due to the evolving nature of microbial contaminants across varying conditions in different commodities and growing regions. Cost-effectiveness of food safety practices is even more difficult to establish. However, members of the produce industry are in agreement about the main sources of contamination risk and the best practices to reduce them. This consensus has emerged after lengthy discussions between commercial buyers, produce growers, contract growers, grower organizations, agricultural extension, academic researchers, State departments of agriculture, and Federal agencies.

### Commercial Buyers Have Largely Driven Food Safety Standards

A number of growers in the case study were early adopters of food safety practices and audits in the late 1990s and early 2000s. They described the challenges of getting their food safety programs up and running efficiently and discussed their subsequent role in helping other growers implement food safety standards in the 2010s. These early adopters cited their frustration at the seemingly strict standards, especially with regard to recordkeeping. However, after a few years of implementing food safety practices, almost all of these early adopters accepted them as a necessary cost of doing business and integrated food safety activities into their operation management.

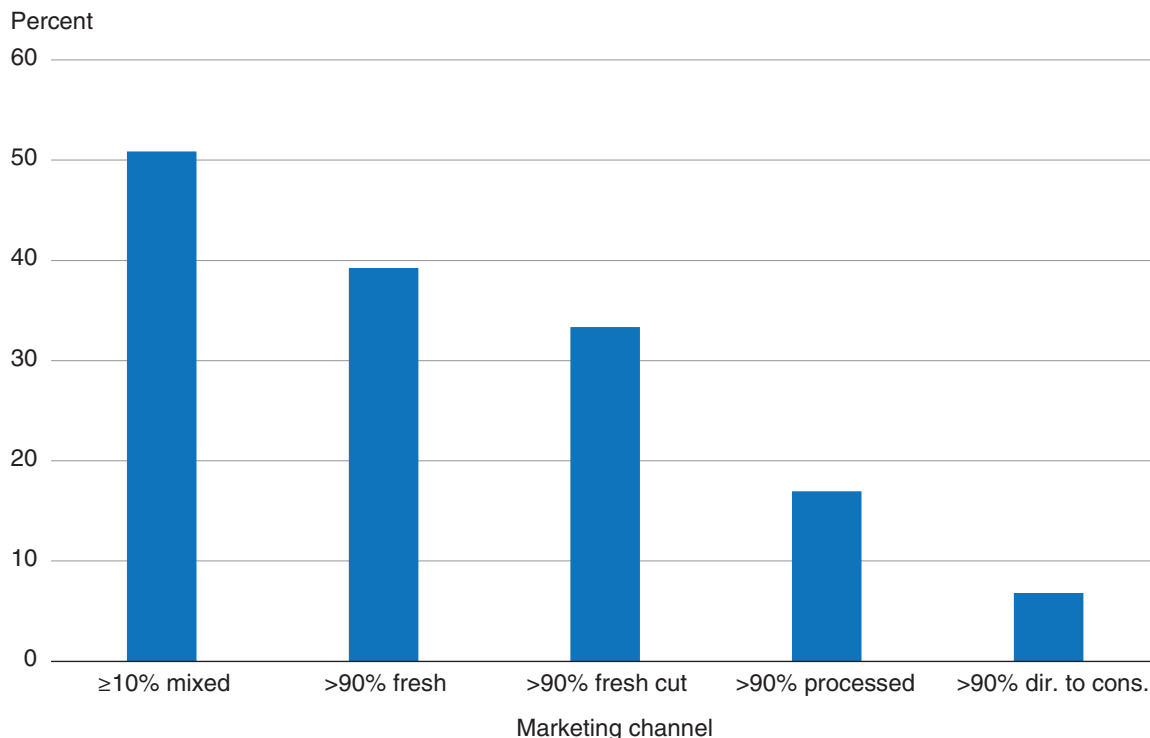
Commercial buyers were frequently cited as the main drivers of food safety standards used on produce operations. Case study growers reported that the first buyers to require food safety audits were those in European or Japanese export markets and large foodservice or processing buyers, with large food retailers following. These growers also noted that selling to government procurement programs required a USDA food safety audit. Many grower-shippers in the study (growers who ship other growers' produce in addition to their own) reported starting with food safety audits in the packing house and later adding field audits. They note that if growers wanted access to these consistent and high-value markets, they had to undergo food safety audits.<sup>4</sup> The ERS/NASS 2015-16 Produce Grower Food Safety Practices Survey shows that growers selling to multiple marketing channels—each of which may have separate food safety requirements—were the most likely to have a third-party food safety audit, while those selling directly to consumers were least likely to have the audit (fig. 4).

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<sup>4</sup>This statement was corroborated in conversations with commercial buyers (Minor et al., 2019).

Figure 4

**Percentage of surveyed produce growers with food safety audits by marketing channel**



Notes: 4,614 growers; the category  $\geq 10\%$  mixed includes growers who do not sell more than 90 percent to one of the four other marketing channels. “Fresh” includes raw agricultural products sold without processing or cooking. “Fresh cut” includes uncooked products that have been minimally processed by peeling, slicing, chopping, shredding, coring, or trimming such as bagged salads, baby cut carrots, or sliced apples.

Sources: USDA, Economic Research Service/National Agricultural Statistics Service, 2015-16 Produce Grower Food Safety Practices Surveys.

In market channels moving smaller volumes of product, food safety audits may not be as widely implemented. For example, Canadian buyers were reported to typically ask for a Leafy Greens Marketing Agreement (LGMA) audit, but a few growers participating in the case study reported that absent a recent outbreak in leafy greens, some Canadian buyers would not require an LGMA audit. Also, case study growers in California reported that they had seen other growers describe their product as “muskmelon” instead of “cantaloupe” to bypass the California Cantaloupe Advisory Board, which requires food safety audits. Generally, growers reported that a buyer not requiring food safety audits tended to be a smaller chain, broker, or repacker (an entity that aggregates produce from various growers or shippers to ripen, resort, or repackage for sale). Growers reported that some larger buyers might be willing to compromise on food safety audits if they need product to fill an immediate, short-term need.

**Role of Food Safety Leaders Within an Operation**

Many growers in the case study who had not previously implemented formal food safety practices expressed worry that new buyer standards or the PR would be a significant burden to their operations without greatly reducing the risk of food contamination. On the other hand, growers convinced of the importance of formal food safety practices often were (1) connected to a commodity that had experienced an outbreak, (2) familiar with the field of public health via their personal background, or

(3) associated with a regional grower organization or State department of agriculture that prioritized produce food safety.

Case study growers reported various approaches to achieve the complementary goals of reducing contamination risk and meeting food safety standards, as in a previous case study of California leafy greens growers (Calvin et al., 2017) where all growers in the study performed practices beyond those required by LGMA (Leafy Greens Marketing Agreement) for their own convenience, risk-management needs, or to meet buyer requirements. Growers experienced with food safety standards were typically well versed in the current scientific literature on food safety. With a series of private audits, growers can flexibly develop a food safety program that attains enough points to pass an audit and also reduces their estimated risk of contamination. For example, a grower using an older packing house without walls would amass 0 points toward a passing score, but other pointworthy improvements or practices—for example, keeping surfaces and equipment clean, materials organized, and records of relevant activities—might be sufficient to reduce the risk of contamination to pass the audit.

In contrast, the PR does not assign points toward a passing score, but allows growers subject to the legislation some flexibility in how they reduce the risk of microbial contamination. For example, the PR specifies that all personnel who handle produce covered by the rule “must receive adequate training, as appropriate to the person’s duties, upon hiring, and periodically thereafter, at least once annually” (FDA, 2015a). The PR further specifies the topic areas that should be covered by the training, but does not require a specific curriculum for specific workers. Under the PR, growers can adjust trainings to fit their own situation as long as they meet the broad standards of the rule.

A common theme among case study growers experienced with food safety was the need to establish a culture of food safety and integrate food safety throughout the operation. For example, a grower is unable to constantly monitor the food safety practices of harvest and packing workers who may find such practices inconvenient or unimportant. However, growers discussed the importance of clearly explaining to workers the reasoning behind the standards throughout training to better foster a culture of food safety. After a few years of consistent implementation, growers reported that food safety was integrated with everyday activities and that everyone knew their food safety responsibilities. Growers noted that frequent reinforcement through formal trainings and signage, as well as through informal correction and guidance, was required to maintain a culture of food safety.

Growers in the case study who were experienced with food safety consistently agreed that starting the program was expensive, confusing, and time-consuming. A few of these growers mentioned that training food safety supervisors and employees would be especially expensive for growers who had to hire an outside consultant to navigate the standards. Some of these growers suggested that a central repository of training materials and example documents in English and Spanish would be the biggest help for growers starting from scratch.

In organizations where a food safety supervisor was primarily responsible for food safety, instead of the grower, the two parties described how they collaborated to integrate food safety into the operation. The food safety supervisors and the growers discussed their frequent communication and mutual respect for each other’s goals. A few food safety supervisors had advocated an expensive capital upgrade to enhance food safety (such as a new cooler, a packing house with sanitizable walls, or sorting/packing equipment with sanitizable surfaces). When evaluating costly food safety investments, growers reported weighing the benefits of reducing microbial contamination risk and meeting buyer requirements.



## Professional Networks Have Helped Growers Develop Food Safety Programs

Many growers in the case study attributed their success in implementing a food safety program to the support they received through their professional networks.<sup>5</sup> Growers experienced with food safety consistently emphasized the importance of talking with other farmers in the region or industry, attending trainings, working with extension agents, or participating in grower associations when starting up their food safety programs. Growers reported that they better understood how to successfully implement food safety practices by talking with others in the industry. Implementing food safety practices from scratch may be difficult for some independent-minded growers who have always done everything on their own or who are hesitant to share information with competitors.

Participating growers described one channel of communication that flows from large grower-shippers to contract growers. Grower-shippers with a well-established brand commonly contract with other growers to grow produce sold under their label. Grower-shippers who had contract growers, as well as contract growers themselves, reported that food safety started with the grower-shipper. After the grower-shipper had a year or two of experience with food safety audits, the contract growers began to undergo food safety audits, often under the guidance of the grower-shipper. Some grower-shippers facilitated practice audits and training.

Many growers mentioned that a few contract growers, predominantly small, went out of business or retired in the face of new food safety standards. However, in most cases contract growers reportedly adjusted. In some cases, when grower-shippers in the case study first began asking their contract growers for food safety records, they reported that the contract growers offered significant pushback and the grower-shippers gave contract growers more time to adjust; growers see pushing back against buyer requirements to be less of an option. Due to liability in the case of an outbreak, growers reported that they did not expect large food retailers (or grower-shippers) to accept a small supplier having a PR exemption, calling into question whether small growers will be able to find willing buyers without having implemented food safety practices, even if they are not legally required to.

In most cases, growers reported that commercial buyers required the same food safety standards from all growers. Sometimes buyers who wanted to establish food safety programs among their longtime growers were reported to provide support during the initial startup period. Support and responsibility was not always clear for all sectors in the market, however. A few growers reported that they began undergoing food safety audits because a buyer started to require it, only to have the buyer decline to purchase from them and instead purchase from an unaudited grower who sold less expensive produce.

## Grower Organizations, Agricultural Extension, and State Departments of Agriculture

Regional commodity organizations, agricultural extension offices, and State departments of agriculture enabled multiple channels of communication between growers, regional organizations, and national organizations. Case study growers connected to these organizations reported feeling much

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<sup>5</sup>Social learning and network effects in the adoption of agricultural technologies and practices have been widely studied, beginning with Grilliches (1957) and Rogers (1962), furthered by Foster and Rosenzweig (1995), Conley and Udry (2010), Läpple et al. (2016), and Garbach and Morgan (2017).

better prepared regarding food safety standards, including the PR. Growers who did not have the support of these groups reported feeling much less confident in their ability to meet private food safety standards or the PR. Agricultural extension (see box) and regional commodity organizations played a role in establishing food safety standards and helping growers comply with them.

Food safety science and standards are diffused through the produce industry in a number of ways: via direct commercial relationships, regional commodity organizations, agricultural extension, State departments of agriculture, the USDA, and the FDA. Many case study growers viewed maintaining these communication channels as key for the dissemination of food safety knowledge. This suggests that identifying growers who are not plugged into major food safety communication channels and finding ways to communicate with them could help expand the PR's reach.

### **Agricultural Extension and Produce Growers**

According to growers, extension agents, and regional commodity organization representatives who participated in the case study, extension agents and regional commodity organization representatives met regularly with growers to hear the issues they are facing firsthand. Extension agents and commodity organization representatives reported exchanging information with their counterparts in other regions and commodities, as well as with national trade organizations and Federal stakeholders like the USDA and FDA. The line of communication extended back to growers as well because extension agents and commodity representatives reported passing on the information to growers that they received from national trade organizations and Government agencies.

Additionally, agricultural extension helps produce and interpret scientific findings for industry use. Agricultural extension has helped develop standards for commodity organizations like LGMA, the California Cantaloupe Advisory Board, and others. Agricultural extension has worked with growers and regional commodity organizations to perform research addressing regional or commodity-specific issues such as the effectiveness of sanitization in wooden versus plastic harvest containers used in Northwest apple orchards (Killinger and Adhikari, 2015) or microbial die-off post-irrigation for commodities in different climates (Ivanek and Wiedmann, 2018; Gutierrez-Rodriguez et al., 2017).

Regional commodity organizations enable growers to pool their resources to fund research addressing their specific food safety concerns. Some regional organizations have tried to expand their outreach to growers in more isolated regions, but many successful organizations were founded by growers with common regional, climatic, and market interests. Growers not connected with agricultural extension or regional commodity organizations reported few outside resources available to aid in their adoption of the new food safety standards, including the PR.

# Uncertainty Surrounding the PR and Food Safety in Produce

The case study suggests that communicating clear, accurate, and timely information to produce growers on PR standards through diverse channels could help to diminish the uncertainty that has pervaded the industry. Growers of all types who participated in this case study were unsure of exactly what the PR requires. Some had already adopted strict practices that would meet anticipated PR standards while others had taken a wait-and-see approach. In a 2015-16 USDA survey, 71 percent of growers who used untreated groundwater in the field tested it at least once annually, as currently required by the PR, while only 15 percent who used untreated surface water in the field tested it at least five times annually, as required by the PR (Astill et al., 2018).

Case study growers expressed varying degrees of confusion on key aspects of what the PR requires. Some growers expected that the PR would minimally impact growers who had already implemented formal food safety practices and would bring all growers up to the same food safety standard. Some even expressed hope that the PR may encourage a single audit standard and broad standardization across different buyers.

## Sources of PR Confusion and Sources of Information

The confusion on PR standards appears to stem from a few different sources. The rule itself is an intricate legal document. At the time of the case study discussions, draft guidance was being published and the train-the-trainer program administered by the Produce Safety Alliance was ramping up (PSA, 2018). However, the knowledge of trainers (both official and unofficial) seemed to be highly variable; some knew the industry extremely well, but not the law, or vice versa. Official guidance and training for growers—vital for a clear understanding of how growers are to implement PR standards—began in the months before the first compliance dates for large growing operations in January 2018 (FDA, 2017a). Around that time, the FDA also announced that onfarm inspections would be delayed until 2019 and that they would be focusing on training both producers and inspectors (FDA, 2017b).

The multiple revisions of the Produce Rule had also contributed to grower confusion. Case study growers most commonly discussed their trouble understanding standards on water testing, manure use, and FDA inspections, as well as the integration of current audit standards. For example, the mandated FDA water test, in a draft rule, was not the industry standard, and many case study growers were concerned that their practices would not be accepted even though their commercial buyers believed them to be sufficient to reduce the risk of microbial contamination. Quite a few growers voiced frustration over a standard that does not appear in the final rule: a 24-hour turn-around time for water tests that they felt was impossible to attain. It was not clear whether the turn-around time had been a potential standard discussed in previous iterations of the PR or whether it was a misinterpretation.

Acknowledging growers' concerns regarding the PR water standards, in November 2017, the FDA extended compliance dates for the water standards an additional 2 years beyond the original 2-year delay (i.e., 2022 for the largest growers; FDA, 2017c). Also at that time, the FDA published its intention to work with stakeholders to explore how they might simplify the PR water standards (FDA, 2017d). In discussions, growers were heavily focused on water testing, and their confusion over

PR water standards may have elevated this issue above other, possibly more costly, ones. ERS cost estimates of onfarm food safety practices from both the 2012 leafy greens case study (Calvin et al., 2017) and the 2015-16 survey (Astill et al., 2018) indicate that water testing is the least costly of any measured food safety practice.

Part of the case study growers' confusion arose from interpreting how the PR, as written, applied to the produce industry. However, multiple growers stated their confusion over whether they would be subject to the more stringent Preventive Controls (PC) Rule designed for food manufacturers that pack or consolidate some of their neighbors' product. Additionally, some growers were unclear if they would be covered as food manufacturers if their packing house was located separately from their fields, even if it was just down the road. Numerous growers suggested that the ambiguity of the rule might induce them to pack produce in the field to ensure compliance even though the industry views a separate packing house as providing a higher level of food safety. During the time of the case study, FDA published draft guidance addressing these questions on whether growers would be covered by the PC Rule (FDA 2016a).

In January 2018 (after this case study was completed), FDA announced that it would use enforcement discretion for certain growers that would have been covered by the PC Rule, such as those that pack or consolidate more product from their neighbors' farms than from their own, or those that color, dry, or dehydrate their product (FDA, 2018e). Other efforts of the FDA to communicate PR standards to growers and to support their adoption include:

- Conducting On-Farm Readiness Reviews in coordination with the National Association of State Departments of Agriculture (NASDA),
- Developing the Produce Safety Network to provide educational visits and technical assistance to growers and other industry stakeholders,
- Developing the FSMA Collaborative Training Forum with USDA, and
- Awarding more than \$50 million to fund the State Produce Implementation Cooperative Agreement Program for the development of State produce food safety programs (FDA, 2018f).

In May 2018, USDA's Agricultural Market Service (AMS), working with FDA and grower organizations, released the Harmonized GAP (Good Agricultural Practices) standard, which integrated PR standards with the USDA GAP standard (USDA AMS, 2018b). In October 2018, FDA released additional draft guidance on the definitions and standards contained in the PR (FDA, 2018g) and the definitions and standards contained in the PC Rule as they apply to fresh-cut produce (FDA, 2018h).

At the time of the case study, growers repeatedly cited the lack of official guidance documents as causing confusion over PR standards. Even many growers who had been operating with formal food safety practices for years expressed uncertainty over what, specifically, they would have to change to meet PR standards. Growers less experienced with formal food safety practices were much more confused with what they would have to change to meet PR standards. Growers reported being unable to determine what changes they would have to make with regard to PR standards until they received and understood official FDA guidance. This uncertainty delays investment decisions.<sup>6</sup> Multiple

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<sup>6</sup>Previous research has indicated that uncertainty promotes the delay of capital investment or the adoption of new production practices (Maart-Noelck and Musshoff, 2013; Baerenklau and Knapp, 2007; Tauer, 2006; Isik et al., 2005; Isik and Yang, 2004; Diederer et al., 2003).



growers reported that they were considering making capital investments related to food safety, but that they were waiting to hear the final word on the PR.<sup>7</sup>

## Uncertainty Surrounding Qualified Exemptions in the PR

Due to the nuances of local and regional produce markets, case study growers often expressed uncertainty regarding PR implementation and enforcement. The PR defines 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 consumers 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 of the PR's technical standards, but must prominently label packaged produce with, or prominently display at the point of sale, the business name and address of the farm where the produce was grown.

Most of the medium to very small growers in the case study sold directly to consumers through pick-your-own, farmers' markets, roadside stands, and community-supported agriculture, or sold directly to restaurants or retail. These growers often talked about maintaining their brands, especially in the context of the local and regional economy. Growing for direct marketing is most prominent in areas surrounding urban and suburban centers (Lohr et al., 2011) and was used by some growers in the case study in all regions of the case study. (The 2011 *E. coli* O157:H7 outbreak in Oregon strawberries involved produce marketed directly to consumers; see box, "Strawberry Background.")

Growers wondered how the PR may affect farm organization decisions. Growers asked whether an operation that sells \$50,000 annually would be able to divide into two growing operations that each sell \$25,000 annually, neither of which would be covered by the PR. Growers also discussed the possibility of avoiding business growth to remain under a PR coverage threshold or shrinking their business to move sales below a PR coverage threshold.

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<sup>7</sup>FDA's decision to stagger compliance dates 1 year for growers with \$250,000-\$500,000 in annual produce sales and 2 years for growers with \$25,000-\$250,000 in annual produce sales may benefit those growers who can delay incurring the costs associated with compliance.

## Strawberry Background

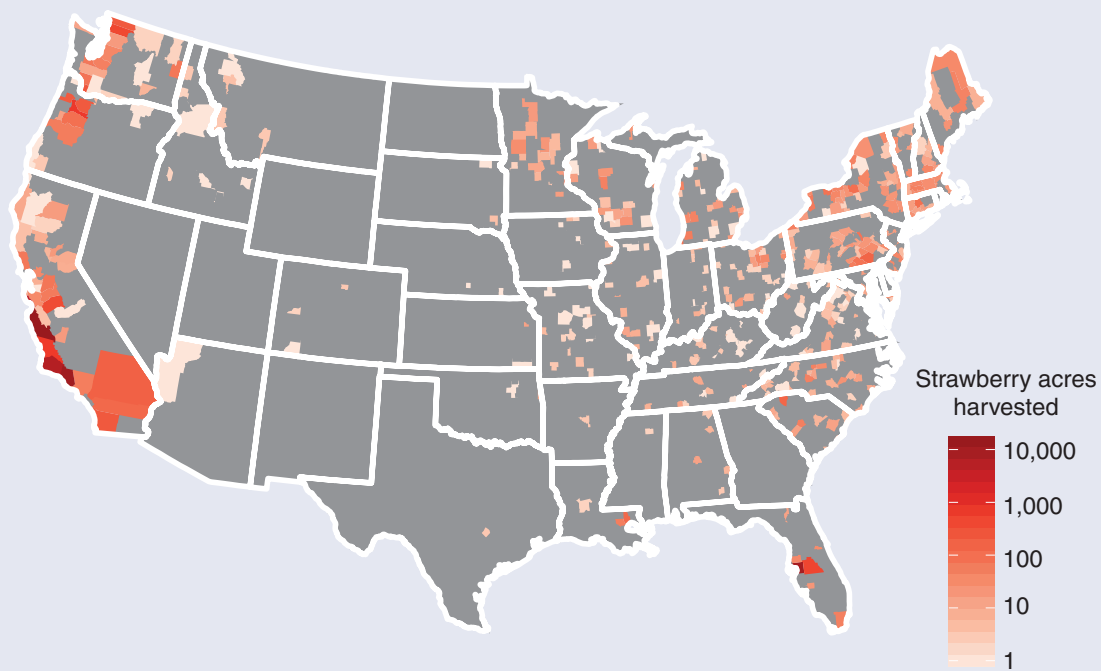
Strawberries are grown on short plants close to the ground. Most strawberries are grown using plastic to cover the soil to maintain temperature and moisture. While strawberries are grown in many States, the California coast provides an ideal climate: moderate year-round temperature of warm days and cool, foggy nights and low humidity (Pollack and Perez, 2005). In 2012, California harvested about two-thirds of strawberry acres in the United States. Four counties contained 95 percent of California strawberry acres: Monterey, Ventura, Santa Barbara, and Santa Cruz (box fig. 2.1). Florida harvested 18 percent of U.S. strawberry acres, 94 percent of which was in Hillsborough County.

U.S. fresh strawberry per capita availability increased from about 5 pounds in 2000 to about 8 pounds in 2016 (Perez, 2017). About 11 percent of strawberries consumed in the United States are imported and about 9 percent of strawberries produced in the United States are exported (Perez, 2018). Imports peak in February and March prior to the U.S. strawberry harvest.

Multiple foodborne illness outbreaks involving strawberries occurred between 1998 and 2016 (box fig. 2.2). The two most prominent outbreaks were the 2011 *E. coli* O157:H7 outbreak and the 2016 Hepatitis A outbreak. In 2011, strawberries contaminated with deer feces from a farm in Oregon made 15 individuals ill, sent 7 to the hospital, and killed 2. Some of the berries were sold at roadside stands and farmers' markets (Rothschild, 2011). Frozen strawberries imported from Egypt were implicated in the 2016 multistate outbreak of Hepatitis A that sickened 137 individuals and sent 57 to the hospital (FDA, 2016b).

Box figure 2.1

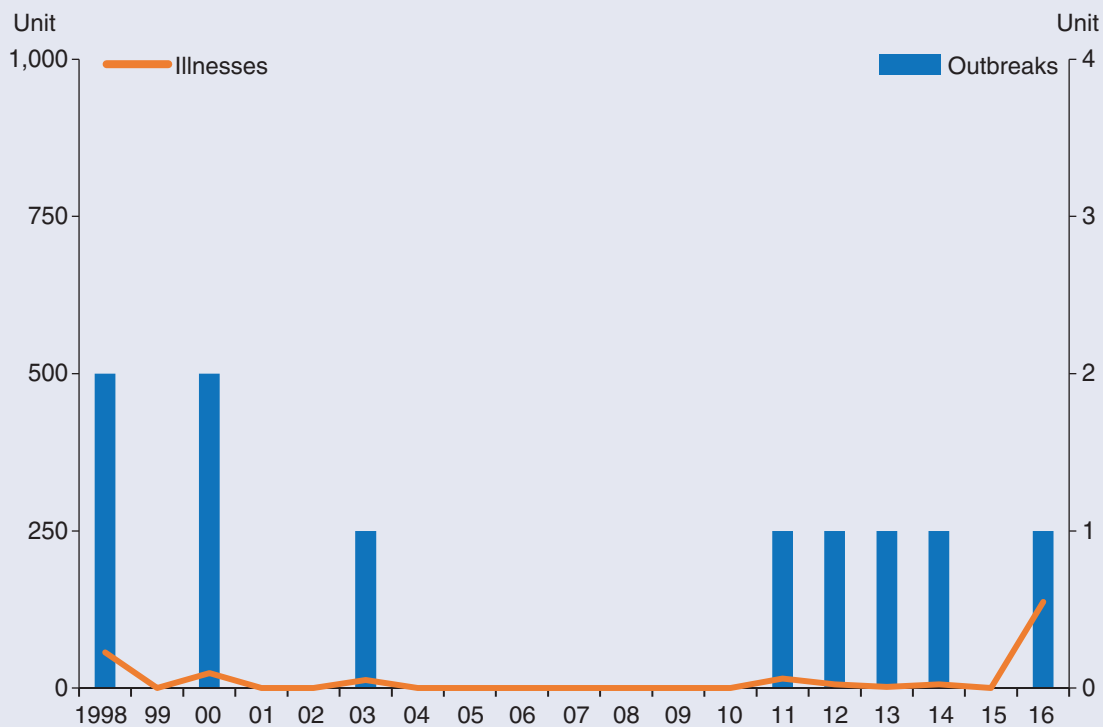
### Strawberry acres harvested by county



Source: USDA, National Agricultural Statistics Service (2015), 2012 Census of Agriculture.

Box figure 2.2

**Illnesses and outbreaks associated with fresh strawberries, 1998-2016**



Note: Includes outbreaks for which strawberry is the sole contaminated ingredient, or if not, the sole food vehicle. Excludes cases of norovirus.

Source: Centers for Disease Control and Prevention, 2017.

## Uncertainty in the Supply Chain and Liability

Most growers who participated in the case study voiced concerns over the uncertainty regarding their potential liability in the event of a foodborne illness outbreak, even if they had passed third-party food safety audits or met PR standards. Growers were quick to point out that following best practices does not entirely eliminate the risk of contamination. These concerns may be heightened following a 2018 *E. coli* outbreak in romaine lettuce that led to 210 illnesses and 4 deaths that FDA traced back to production in the Yuma, Arizona, region where the majority of growers followed the strict LGMA standard (FDA, 2018b).

Because produce crops are highly seasonal, dispersed, and perishable, produce markets are highly dynamic and complex. The business arrangements and types of growers in the produce supply chain are diverse because both growers and buyers need flexibility to respond to market changes in a timely manner. All growers stressed the importance of producing safe food, but they did not always agree upon which practices should be used, while demonstrating a wide range of knowledge of food safety standards and science. Also, the science of food safety is advancing monthly, with many contamination risks still unknown or disputed. Certain growers and buyers have been at the forefront of implementing food safety practices and audits for years. Other growers and buyers have recently followed suit. Some growers felt unable or are reluctant to implement formal food safety practices.

Some growers in the case study posited that an underlying tension between growers and their buyers over prices and the timing of payments can carry over to concerns about assignment of liability for food safety outbreaks and the role of food safety audits in transferring liability. A few growers used the term “arms race” to characterize some buyers’ increasingly strict audit standards, which these growers felt were not supported by scientific evidence. Some growers suggested that buyers prioritized transferring liability for an outbreak over reducing the risk of an outbreak. Growers often expressed unease that they could not transfer liability the way that they felt their buyers could.

For both growers and buyers, a foodborne illness outbreak is a looming threat with the potential for bankruptcy in the aftermath of a sufficiently severe outbreak (see box, “Cantaloupe Background”).<sup>8</sup> Because the point of contamination in a supply chain is difficult to pinpoint, growers feared the possibility of their product leaving the farm clean, becoming contaminated further down the supply chain, then erroneously traced back to them. This uncertainty, pervasive throughout the supply chain, was closely tied to liability concerns for many growers.

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<sup>8</sup>Examples include Peanut Corporation of America in 2008 (Hussain and Dawson, 2013) and cantaloupe-grower Jensen Farms in 2012 (Booth, 2012).

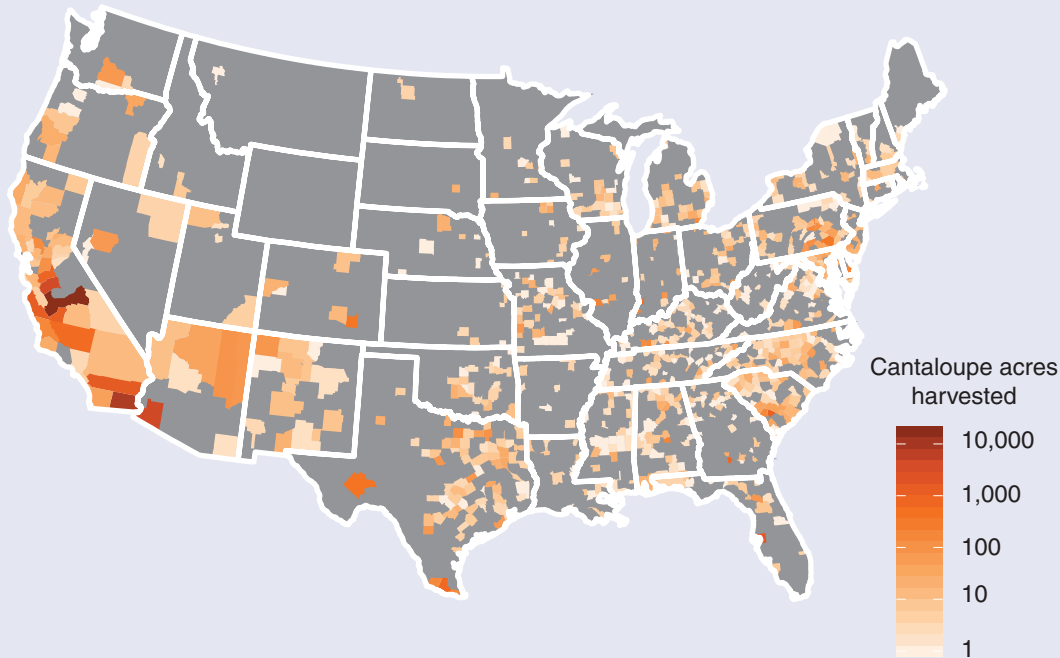
## Cantaloupe Background

Cantaloupe is a melon, related to cucumbers, grown on vines on the ground. In 2012, California produced more than half of U.S. cantaloupes, and Arizona produced a little more than one-quarter (Box fig. 3.1). Georgia and Florida produced a little under a tenth. The vast majority of cantaloupe is sold fresh, some of which is sold fresh-cut. U.S. per capita availability of cantaloupe decreased from about 11 pounds in 2000 to about 7 pounds in 2016 (Perez, 2017). About one-third of cantaloupe consumed in the United States was imported in 2000, rising to about 45 percent in 2016. Imports peak in March and April. On average, 9 percent of U.S. cantaloupe production was exported over the past decade. The share of U.S.-grown cantaloupes going to foreign markets rose from 6 percent in 2000 to 9 percent in 2016 (Perez, 2018).

Since 2000, cantaloupe has been associated with multiple outbreaks (Box fig. 3.2). The two most prominent multistate outbreaks occurred only a year apart. In 2011, *listeria monocytogenes* on cantaloupe from a Colorado farm made 147 individuals ill, of which 143 were hospitalized and 33 died. Facing 6 years in jail and \$1.5 million in fines, the owners of the farm pled guilty to six counts of introduction of adulterated food into interstate commerce and received 5 years' probation, 6 months' home detention, and \$150,000 each in restitution fees to victims (Andrews, 2014). In 2012, a cantaloupe farm in Indiana was tied to an outbreak of *Salmonella* that sickened 261 individuals, hospitalized 94, and killed 3 (CDC, 2017).

Box figure 3.1

### Cantaloupe (fresh-market) acres harvested by county



Source: USDA, National Agricultural Statistics Service (2015), 2012 Census of Agriculture.

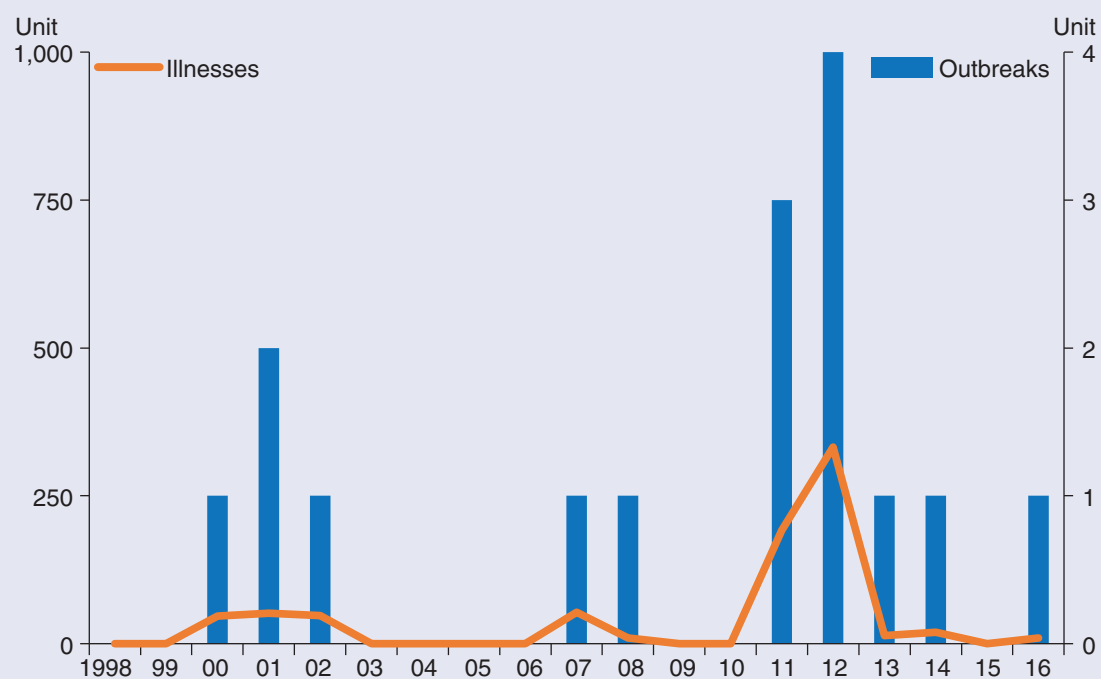


Cantaloupe growers in our case study discussed a few issues unique to their production. In the Southwest, cantaloupe is produced in a desert environment and heavily irrigated; growers there are especially concerned with water testing standards. Larger cantaloupe growers in the Southwest generally tested their irrigation water as their third-party food safety audits required. Southwest growers maintain that the dry air and nearly constant sunlight keeps microbial contamination levels in the fields much lower than in more humid production regions. Due to the dry production environment and their perception that they could introduce contamination through washing, growers in the Southwest generally did not wash cantaloupe before packing in the packing house. However, one grower washed a subset of cantaloupe that was destined for a specific retail buyer who required a specific wash standard.

In the Southeast, washing cantaloupe with a disinfectant prior to packing was standard and required a large investment in washing line equipment and constant monitoring by packing line workers. Cantaloupe growers across regions are highly aware of previous contamination events where old washing and drying equipment had been repurposed to wash cantaloupes and where food contact surfaces—often wet—were made of wood, felt, or carpet and were incapable of being properly sanitized.

Box figure 3.2

**Illnesses and outbreaks associated with fresh cantaloupes, 1998–2016**



Note: Includes outbreaks for which cantaloupe is the sole contaminated ingredient or, if not, the sole food vehicle. Excludes cases of norovirus.

Source: Centers for Disease Control and Prevention, 2017.

## Growers Face Many Constraints in Addition to Food Safety and the PR

Growers in the case study talked about the importance of growing safe, high-quality food for their customers, but explained that their product and operation had to meet many additional requirements to be profitable. Growers listed as factors competing with food safety for a grower's time and resources: other legal requirements, domestic competition, foreign competition, labor shortages, environmental requirements, water issues, weather, accessibility to buyers, payment from buyers, and market fluctuations.

Growers often conflated food safety—or at least talked about it together—with chemical safety and worker safety. Each of these has Government-mandated requirements, and in most operations, the same individual is responsible for recordkeeping mandated by food, chemical, and worker safety regulations and certification programs. Some growers contended that the array of regulations that already apply to the U.S. grower should inform how the additional cost of the PR is measured. The belief held by many growers that various regulations affect only domestic growing operations and make it harder to compete with international growers fed into growers' frustrations.

On the other hand, growers who had suffered through a drop in demand after a foodborne illness outbreak in their respective commodity lamented how one grower could spoil the market for everyone else when it comes to food safety (see box, "Apple Background"). These growers often discussed the importance of finding ways to prevent microbial contamination on *all* farms, but had differing opinions on whether standards enforced through commodity organizations or the Federal Government would best accomplish this goal.

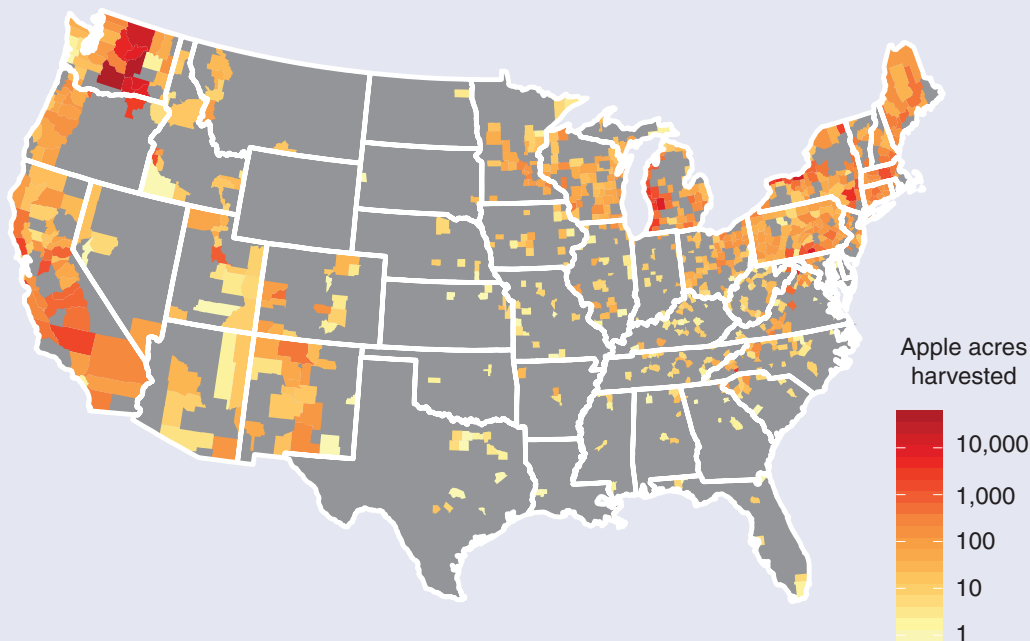
## Apple Background

Apples are a tree fruit commonly consumed fresh, but they are also consumed in many other forms after processing. In 2012, Washington produced nearly two-thirds of U.S. apple output and three-quarters of fresh-market apple output (Box fig. 4.1). About two-thirds of U.S. apple output is sold to the fresh market and about a third to the processing market. About a quarter of U.S. fresh apple output is exported, and about 7 percent of fresh apples consumed in the United States are imported (Perez, 2018). (Imports peak in June and July before the U.S. crop is harvested.) Prices for fresh-market apples are significantly higher than for processing apples; apples that are too blemished or undersized for the fresh market are often diverted to the processing market (Perez, 2016). U.S. per capita availability of fresh apples has averaged 17 pounds over the past decade, and the number of varieties has increased (Perez, 2017).

Apples have commonly been viewed as safe from microbial contamination because the fruit grows away from potential contamination on the ground and in irrigation water. However, like all produce, contamination can be introduced during harvest, handling, packing, or processing. Since 1998, most bacterial contamination involving apples has occurred in unpasteurized apple cider (Box fig. 4.2). In 2014, the first deaths caused by foodborne illness linked to U.S. apples were attributed to caramel apples contaminated with *listeria monocytogenes*. Of the 35 individuals sickened, 34 were hospitalized and 7 died. Subsequent research indicated that piercing apple skin with a stick greatly increased the growth of *listeria monocytogenes* in caramel apples, possibly contributing to a more favorable bacterial environment by releasing juice (Glass et al., 2018). Even though the 2014 apple outbreak was tied to one relatively small grower-processor in California, Washington growers lost a reported \$15 million in sales to export markets when foreign buyers reacted to news of a foodborne illness outbreak in U.S. apples (Beecher, 2016).

Box figure 4.1

### Apple acres harvested by county

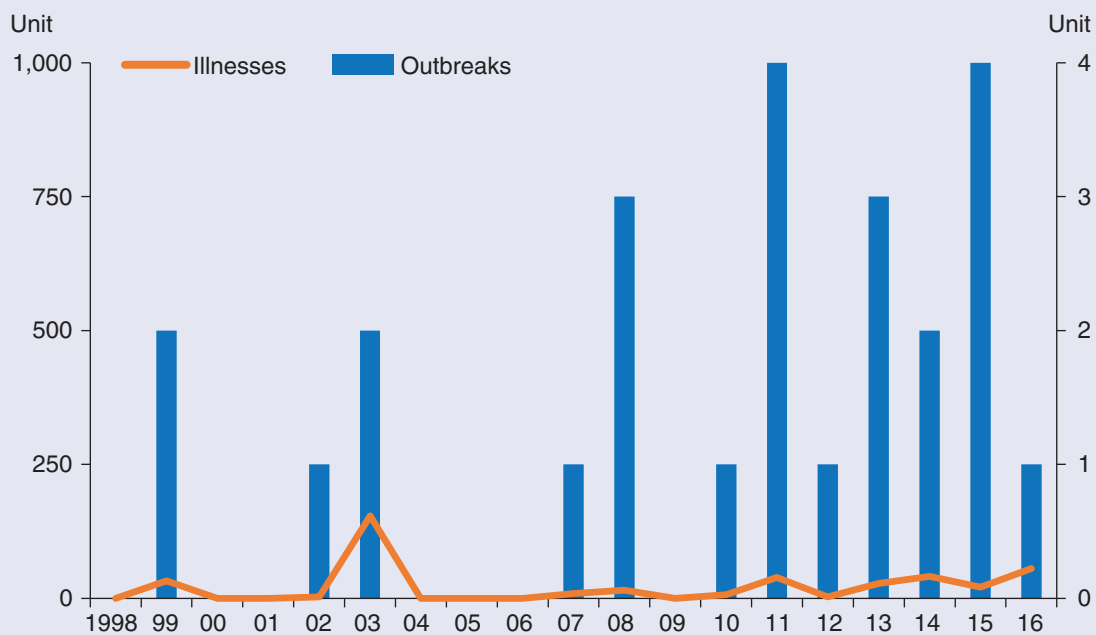


Source: USDA, National Agricultural Statistics Service (2015), 2012 Census of Agriculture.

Apple growers in our case study voiced concern that the PR may have required the use of plastic bins for transportation from the field to the packing house due to sanitation considerations; plastic bins cost three times more than wooden bins. Many organic apple growers had already switched to plastic bins since some apple varieties have thinner skins that can be damaged by wood. Apple growers also cited the differences in PR-related training costs for those using mechanical harvest versus those relying on large teams of harvest workers. Apple growers in the Lake States and New England, in competing with the market-dominant Washington growers, were looking to differentiate their product as locally grown or to expand into value-added products like cider or hard cider. When selling as a local producer, apple growers reported that different retail chains had different food safety standards, all of which had become more strict over the years. While cider and hard cider offered higher sales value, their production involved additional food safety standards and other State regulations.

Box figure 4.2

**Outbreaks associated with fresh apples, 1998-2016**



Note: Includes outbreaks for which apple is the sole contaminated ingredient, or if not, the sole food vehicle. Excludes cases of norovirus.

Source: Centers for Disease Control and Prevention, 2017.

## Challenges in Implementing Food Safety Practices

Although consistent themes emerged from case study discussions, certain food safety provisions were reported to impact various types of growers differently. Many of the contributing factors to these differences are out of a grower's control. Factors such as size of the operation, activities conducted on the farm, crop variety, and even region dictated different food safety practices to reduce the risk of contamination. Despite the differences, smaller and less experienced growers reported generally facing the biggest changes to meet new food safety standards.

### Capital Investment Is Most Difficult for the Smallest Growers

Growers in the case study who have done the least regarding food safety practices are those that face the highest cost to meet new food safety standards, including the PR. Some growers were trying to learn and adapt as quickly as possible, while others seemed to be waiting until the last minute to make any changes. Some growers mentioned neighbors who in the previous few years had decided to sell their operations rather than invest capital to make facilities conform to new food safety standards demanded by buyers. They expected the PR to have a similar effect.

Growers note that capital investment for facilities or equipment with better food safety features is expensive. Older buildings often need to be replaced or renovated with interior walls that can be sanitized. Likewise, older equipment needs to be replaced or refurbished such that all food contact surfaces can be readily sanitized. While some changes are certainly capital intensive, many segments of the produce market had already required these changes before the PR. Growers selling to smaller (i.e., non-retail chain) channels who had avoided these investments may be forced to choose between making the investments to meet new PR or buyer standards or exiting the market. Data from the ERS/NASS 2015-16 Produce Grower Food Safety Practices Survey show that smaller growers (less than \$250,000 in annual sales) are much less likely to have a third-party food safety audit that would require these kinds of investments (fig. 5).

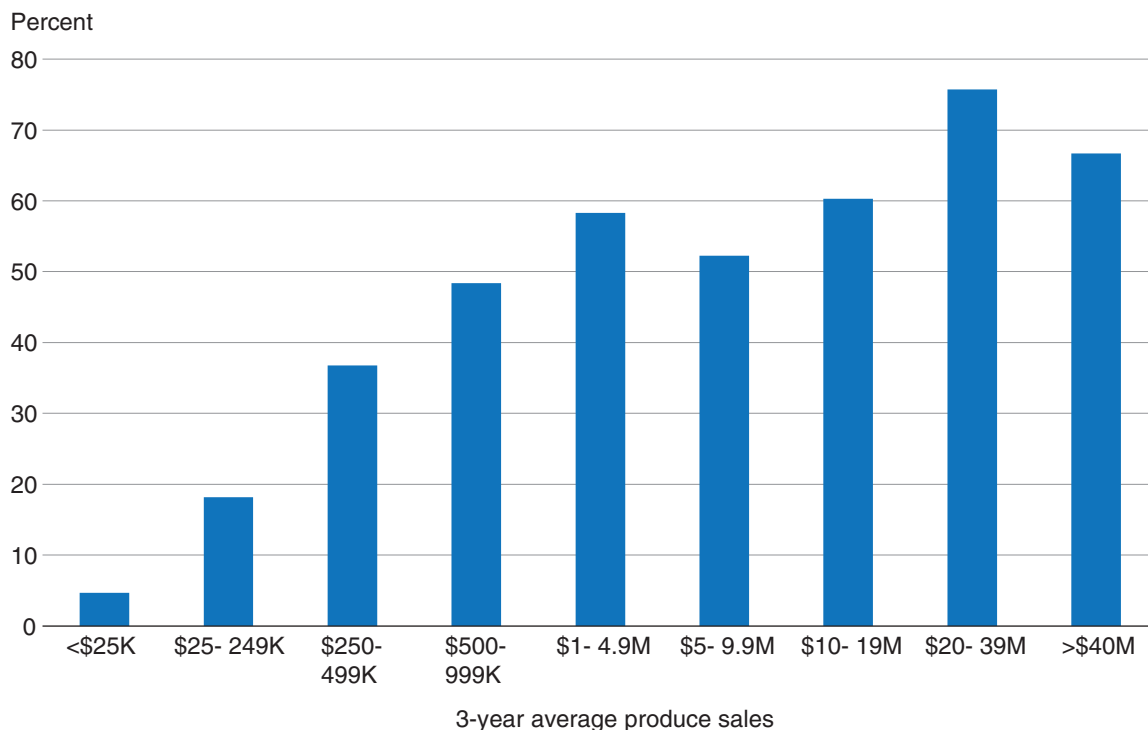
Produce growers in the case study discussed the challenge for small growers to absorb the costs of a food safety program, especially water-related costs. While larger farms may irrigate numerous fields and multiple acres with an irrigation system, many smaller farms pull water from the most convenient source, which may change field by field and crop by crop. This makes testing for water quality much more difficult, time consuming, and costly as numerous sources must be tested and maintained, as opposed to a single source for the entire operation.

Size of operation also impacted the time available for the grower to implement food safety standards for operations that were not large enough to justify employing a separate employee to manage food safety. Most growers said they had little time to study how the science of food safety connects to the various buyer standards and to devise a customized food safety program. Growers without food safety experience and without a food safety supervisor reported being able to understand a set of defined standards like those in the PR, when provided with proper guidance documents. But these growers nearly all agreed that documenting every action would be a severe burden.



Figure 5

**Percentage of growers with food safety audits within sales category (4,452 growers)**



K = 1,000. M = Million

Sources: ERS/National Agricultural Statistics Service 2015-16 Produce Grower Food Safety Practices Surveys.

### Burden and Benefits of Documenting Food Safety Activities

Many growers, with various levels of experience in food safety, described most food safety guidelines as common sense but the required documentation for food safety activities (including standard operating procedures, or SOPs) as overwhelming at first. Many of these same growers understood and supported SOPs after becoming familiar with them, but still expressed frustration with the need to document everything and the specificity of standards that seemed unimportant. However, some growers found that establishing an organized system of food safety documentation enabled them to defend their brand and to organize other aspects of their operation for improved efficiency.

To emphasize the costs of food safety recordkeeping standards, multiple audited growers pointed to a shelf full of binders with their food safety plans, SOPs, and documented practices. While food safety plans and SOPs are necessary for many third-party audits, they are encouraged—but not required—by the PR.

Because of the recordkeeping burden associated with food safety, many of the firms in the case study had recruited a food safety staff person (often a family member) dedicated to recordkeeping, trainings, audits, etc. This person was also typically responsible for other records-intensive duties, such as payroll. Large leafy green growers in California reported that their food safety staff spent, on average, 43 percent of their time on monitoring and documentation (Calvin et al., 2017).

In spite of the frustrations surrounding recordkeeping, some growers use documentation to verify the standards their product meet upon sale. Buyers often aggregate product from many different growers, and they may sell that product to a variety of buyers who may, in turn, sell to other buyers. Tracing through this complex system has been a continual challenge for all entities in the supply chain.

Food safety records may also have a complementary effect on other useful recordkeeping for some growers. In the 2015-16 survey, 13.0 percent of very small growers (less than \$25,000 in annual sales) reported having a written food safety plan, compared to 88.3 percent of very large growers (\$5 million or more in annual sales) (Astill et al., 2018). In our case study, growers of all sizes reported that food safety recordkeeping standards were the impetus for maintaining other records regarding farm management. These growers reported using farm management records to make cost-saving decisions and to increase efficiency.

## Audit Fatigue

Closely related to the costs and benefits of documentation, experienced growers repeatedly brought up what they called audit fatigue. In the 2015-16 USDA survey, 62.1 percent of large growers (\$1 million to less than \$5 million in annual sales) had at least one third-party food safety audit (Astill et al., 2018). In our case study, large grower-shippers reported up to 30 audits, and while a large portion of the elements in each standard overlap, it is still a considerable logistical burden for growers to ensure that the operation is meeting all of the various standards as well as the operation's own internal food safety priorities. Some growers voiced hope that the PR, GFSI, or some other standard would be able to reduce the number of distinct audits required by buyers. It is unclear if the market is moving toward a single food safety standard; alongside the development of GFSI-benchmarked standards, some large retail and foodservice companies have required company-specific riders to be added on to any GFSI-benchmarked audits.

Highlighting the uncertainty surrounding the science of food safety and its impact on liability in the supply chain, multiple experienced growers said they had to educate *buyers* on best practices when the buyers were new to implementing food safety. Multiple growers reported that when some buyers who had previously not required food safety began their own program, and to demonstrate their commitment to food safety, they include one or more stringent standards that the growers argued did not reduce the risk of contamination. After explaining their current food safety practices to the buyer, these growers were usually able to negotiate an acceptable set of food safety standards.

## Food Safety Capacity Constraints

For both experienced growers in the case study and those new to food safety, capacity constraints for food safety staff, food safety auditors, and water-testing labs posed additional challenges under new food safety standards and the PR. Even before the PR, skilled food safety staff were in high demand and were recruited from one grower to another. The skill set required for a food safety supervisor is unique: they are often required to be bilingual, and are required to have a solid understanding of general science. To succeed, they must earn the respect of harvest workers and growers while asserting clear standards on food safety.

The number of qualified food safety auditors is limited. While the PR does not require an audit, it seems likely that more growers would choose to get an audit to demonstrate that they meet most

PR standards at the same time that they meet buyer requirements. If an auditing office was far from a grower, the grower usually had to pay the travel costs of the auditor. In remote areas, growers described regularly driving 2 to 3 hours to hand-deliver water samples to the nearest lab for testing. Nearly every experienced grower mentioned the scarcity of water-testing labs. No one reported using the test described in the PR at the time; many said finding a lab that was able to do the test was difficult, if not impossible.

## Certain Water Application Carries Higher Food Safety Costs

Ensuring water quality was a key concern among case study growers for food safety standards, including the PR. Growers faced different costs of testing due to irrigation needs in different regions and for different crops. Growers commonly pointed out that there was no need to test water if you did not irrigate your crop, thus eliminating a portion of the costs of meeting food safety standards. However, for many crops in many parts of the country, growing without irrigation is not possible (see box, “Onion Background”).

Growers reported using primarily two types of irrigation: drip and overhead spray. Those with drip irrigation believed that with some minimal water testing, they would be able to comply with the PR standards, as their water never touched the edible portion of the produce. However, those with overhead spray irrigation were concerned that simply because of the delivery method, they would be incurring a much larger cost to meet PR standards. This concern was amplified when a grower sprayed for frost or sun protection. Because growers only use frost or sun protection sprays under extreme conditions, growers were concerned that they would be required to maintain records on a water source that they infrequently, or never, apply to a crop.

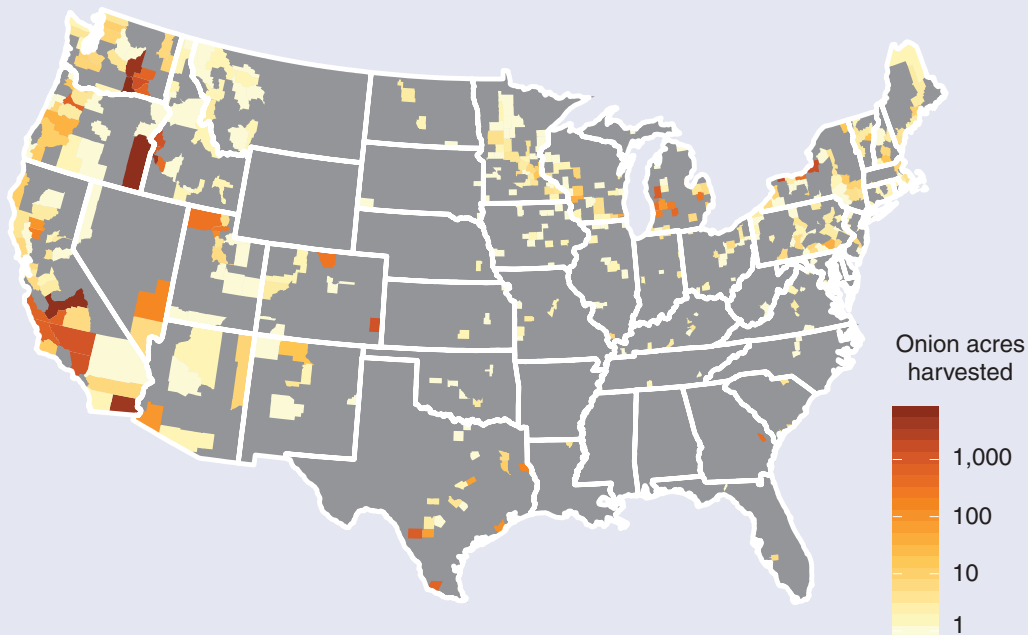
## Onion Background

Bulb onions are a root vegetable. (Green onions, or scallions, are distinct from bulb onions.) The two main categories of onions are milder and more fragile “spring/summer” varieties and stronger and more durable “storage” varieties (Lucier and Plummer, 2003). In 2012, about one-quarter of fresh onion acres were located in California, about one-quarter in Washington, about an eighth in Oregon, and about an eighth in Idaho (Box fig. 5.1). Per capita onion availability has averaged about 20 pounds over the past two decades (Parr et al., 2018a). Onion imports increased from 9 percent of availability in 2000 to 19 percent in 2016 (ignoring onion stocks). Onion exports have remained fairly flat since 2000, averaging 11 percent of production. Other than a dip from June to September, onion imports remain fairly stable throughout the year (Parr et al., 2018b).

Onions (not including green onions) have been implicated in a few foodborne illness outbreaks between 1998 and 2016 (Box fig. 5.2). No deaths were tied to outbreaks where onion was the sole contaminated ingredient or food vehicle. The two most prominent outbreaks were both due to *Salmonella* contamination. In 2010, onion contaminated potato salad sickened 41 individuals and hospitalized 5. In 2016, contaminated onion led to illness in 29 individuals and hospitalization of 6 individuals.

Box figure 5.1

### Onion (bulb, fresh-market) acres harvested by county

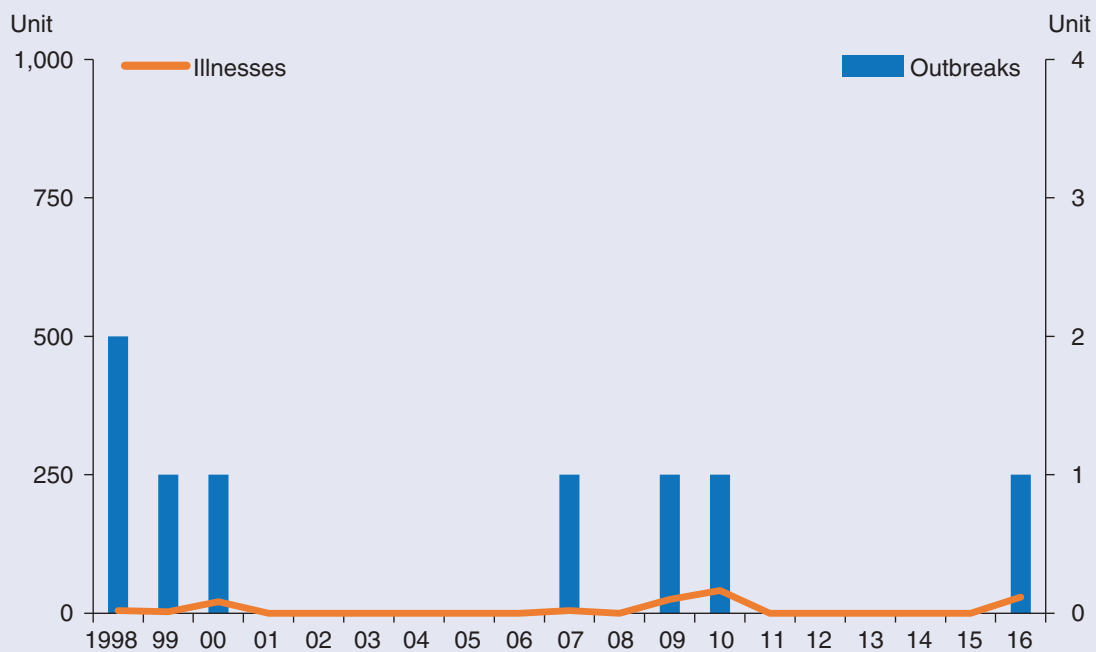


Source: USDA National Agricultural Statistics Service (2015), 2012 Census of Agriculture.

Onion growers in the case study faced almost an opposite set of issues compared to cantaloupe growers. Dry onion growers in the Northwest typically do not use water on the packing line. These growers do not have postharvest water-testing issues, or its associated cost, like growers in other commodities. However, the arid inland region of the Pacific Northwest where onions are grown has a wide-ranging canal irrigation system that is managed by geographically distinct districts. The irrigation canals are constructed to deliver water along a long line of users, and—due to the scarcity of water—the fields are designed to recapture excess irrigation water and feed it back into the canals. This regional irrigation infrastructure would be very hard, if not impossible, to change at this point. Due to hydrology, irrigation wells are equally unrealistic. Onion growers reported that animal intrusion was not as much of an issue for bulb crops like onions.

Box figure 5.2

**Illnesses and outbreaks associated with fresh bulb onions, 1998–2016**



Note: Includes outbreaks for which onion (excluding green onion) is the sole contaminated ingredient, or if not, the sole food vehicle. Excludes cases of norovirus.

Source: Centers for Disease Control and Prevention, 2017.

## Conclusion

Since the late 1990s, Federal agencies like FDA and USDA, third-party audit services, and regional and commodity-specific grower organizations have developed multiple voluntary food safety standards. During the same period, Florida tomato growers and California cantaloupe growers established their own mandatory food safety standards. In 2011, the Food Safety Modernization Act's (FSMA) Produce Rule (PR) became the first set of national regulations governing food safety practices to be used on U.S. farms that sell fresh produce. In January 2018, the PR took effect for the largest growers of produce; other growers will have to comply in 2019 or 2020, depending on sales.

A number of U.S. fruit and vegetable growers representing a variety of locations, sizes, and commodities voiced a clear set of themes in recent discussions with ERS economists. These growers emphasized their concern—beyond legal liability—for the quality of their product and the safety of consumers. They described the newly mandated PR as an additional layer of complication to ever-evolving buyer standards in extremely competitive markets. Similarly, growers commonly cited the challenge of maintaining the extensive records necessary to comply with buyer-required audits and other Federal and State regulations.

The growers in the case study most confident in their ability to adapt to new food safety standards share two key characteristics: a background and culture of food safety at their company and a well-developed information network related to food safety. Both of these characteristics were often associated with formal commodity organizations, marketing partners, or particularly good agricultural extension offices in the area. Growers who had access to this type of support often expressed confidence in their ability to adjust to the PR.

Some growers in the case study had already adopted strict practices that are likely to meet PR standards while others have taken a wait-and-see approach, but growers were unsure of exactly what the PR would require in practice. Official FDA guidance documents and knowledgeable trainers were seen as essential to help growers implement PR requirements—especially for growers with a limited background in formal food safety practices. Moreover, growers consistently expressed that food safety is only one of many attributes that make a produce company viable in the modern market. The largest growers, and those that have been selling to national supply chains, reported being able to absorb the costs of implementing new food safety standards. Smaller growers, and those selling locally, were waiting for more clarity on standards of the PR before making significant capital expenditures.

Prior to the implementation of the PR, growers in the case study who indicated they were experienced in food safety seemed cautiously optimistic that they will be able to meet the standards of the rule with limited adjustments to their everyday practices. In fact, many of these growers referred to new laws as a food safety floor designed to enforce defensible standards but not push the boundaries beyond what the market has already dictated. While some of those in the case study expressed hope that the Federal rules would move the industry toward a single system for food safety, most suggested that this is unlikely in a marketplace where third-party food safety audits are continually updated in response to the latest public health event or scientific finding.



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