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Food Safety Requirements for Produce Growers: Retailer Demands and the Food Safety Modernization Act

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Food Safety Requirements for Produce Growers: Retailer Demands and the Food Safety Modernization Act

Travis Minor, Gerard Hawkes, Edward W. McLaughlin, Kristen S. Park, and Linda Calvin

Abstract

The 2011 Food Safety Modernization Act established “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” commonly known as the “Produce Rule” (PR). Interviews with nine food retailers form a case study of the retail sector’s food safety requirements for produce suppliers and how they might change in response to the PR, which began phased implementation in January 2018. Although third-party audits of food safety practices are commonly demanded by retailers, the PR does not require these audits and provides exemptions and variances for smaller growers or particular commodities. This study, one in a series examining how growers adapt to evolving food safety requirements, found it likely that retailers already requiring third-party audits will continue to do so. Responses also indicated retailers will likely continue to impose food safety requirements on growers uniformly, rather than spend the time and resources to understand and adhere to the nuances of the PR’s compliance criteria. The interviewed retailers noted they lost suppliers in the past when new food safety standards were introduced, and they expect some growers may stop supplying them when the PR takes effect. However, they believe the PR will not drastically affect their growers but will have the greatest impact on growers outside their supply chains.

Keywords: Food Safety Modernization Act, Produce Rule, retailers, food safety requirements, produce, produce growers, food safety audits

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Food Safety Requirements for Produce Growers: Retailer Demands and the Food Safety Modernization Act

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What Is the Issue?

Foodborne illness linked to contaminated produce is a public health concern. The Food Safety Modernization Act (FSMA), signed into law in 2011, is the Federal Government’s most recent effort to reduce the risk of microbial contamination that can cause human illness. The law’s “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” commonly known as the “Produce Rule” (PR), may pose a challenge for farms that grow produce and sell into retail markets.

While the PR is the first Federal regulation focusing on microbial food safety at the farm level, it is not the first effort to improve the safety of produce. Commercial buyers (retailers, foodservice firms, and produce processors) have demanded certain food safety practices from growers for years. Produce growers and grower organizations have also been instrumental in raising food safety standards.

Retailers play an increasingly active role in food safety programs because they are often the final point of contact for consumers before they eat the food, and so consumers may associate the food with the retailer. While the PR does not specifically call for retailers to do anything, retailers have long required growers to have third-party food safety audits, which have helped shape the food safety landscape.

Information on the retail sector is scarce because retailers’ competitiveness and disclosure concerns make them difficult to survey. This report represents a first look at this part of the produce supply chain. Using information from interviews with nine diverse retailers prior to the 2018 implementation of the PR, it focuses on the role of retailers in the development and implementation of food safety standards for produce. It covers the food safety requirements imposed by retailers on their produce suppliers, how the requirements evolved, if the requirements will change when the PR is implemented, and whether retailers will demand more than the PR requires.

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.

What Did the Study Find?

Retailers have required food safety audits for decades to minimize their risk of being associated with a food-borne illness outbreak.

- The PR does not require third-party audits, although it does “recognize the role that third-party audits can play in promoting food safety.” All nine retailers interviewed require audits from their suppliers, although one does not apply the requirement to its smallest suppliers. The retailers expect to continue to require third-party food safety audits to certify that growers conform to the PR.
- Three retailers interviewed require the same types of audits for all their suppliers, large and small. Three retailers allow smaller suppliers to use less demanding reviews. The remaining retailers obtain food safety certifications from wholesalers, which often apply standards uniformly. The PR does not apply to certain small growers.
- Interviewed retailers require audits for all produce and may require more stringent audits for commodities they perceive to carry a greater risk for foodborne illness outbreaks. The PR does not cover certain commodities rarely consumed raw, such as potatoes and beets, but most of the retailers require audits for these commodities as well.
- Some of the retailers have lost suppliers in the past when new food safety standards were introduced because of the increased cost of compliance. They expect this may happen again, particularly for their smaller suppliers.
- Retailers believe implementation of the PR will not drastically affect their growers. Rather, they expect the PR to have its greatest impact on produce growers outside these supply chains (direct-to-consumer sellers, smaller retail suppliers, and other less traditional sellers).

How Was the Study Conducted?

Researchers at Cornell University interviewed retailers using questions developed jointly with USDA, Economic Research Service (ERS) economists. The interviews complied with U.S. Office of Management and Budget rules requiring clearance only for surveys of more than nine people. Interviews were conducted by phone from December 2016 through February 2017. The retailers were selected to obtain the broadest possible geographic representation, a variety of store-format types, and a mix of company sizes. Respondents did not receive any incentives to participate. Given the various formats, sizes, and geographic distribution of the companies interviewed and the range of responses regarding food safety programs and strategies, the results provide insights into the food safety policies of U.S. supermarket companies and how these practices and the PR may affect growers. This report supplements companion studies of statistical survey results and open-ended interviews with produce growers.

Food Safety Requirements for Produce Growers: Retailer Demands and the Food Safety Modernization Act

Introduction

Foodborne illness linked to contaminated produce is a public health concern. In 1998-2008, the Centers for Disease Control and Prevention attributed 46 percent of U.S. foodborne illnesses with a known food vehicle to produce (Painter et al., 2013). The Food Safety Modernization Act (FSMA), signed into law in 2011, is the most recent step in Federal efforts to reduce the risk of microbial contamination that can cause human illness. The FSMA's "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," commonly known as the "Produce Rule" (PR), is the law's most important provision for farm-level produce operations. The U.S. Food and Drug Administration (FDA) released the final PR in 2015, with implementation phased in beginning in January 2018 (FDA, 2015a). The PR establishes a national approach to regulating the safety of fresh produce, shifting the policy focus from reaction to foodborne illness outbreaks to risk-based preventive actions.

The PR is the first Federal regulation focused on minimizing microbial hazards at the farm level. But it is not the first effort to improve the safety of produce. In the mid-1990s, several foodborne illness outbreaks, including ones linked to California lettuce and Guatemalan raspberries, raised awareness of the potential for microbial contamination in produce (table 1).

In 1998, the FDA produced the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," commonly known as Good Agricultural Practices (GAPs) (FDA, 1998). While this guidance contained only nonbinding recommendations, some growers began to alter their practices based on the recommended best practices. The produce industry and commercial buyers (retailers, foodservice buyers, and produce processors) took note of the developing challenge of food safety and have been instrumental in pushing food safety practices forward. Additional large foodborne illness outbreaks linked to produce brought home the negative consequences of being associated with such an event and provided the impetus for retailers to demand new food safety standards and audits from suppliers. Using interviews with a diverse group of nine food retailers, this report focuses on the role of retailers in the development and implementation of food safety programs for fresh produce.¹

Retailers strive to ensure food safety while not having direct control over production practices. Many retail companies have turned to indirect means, using third-party audits, to make certain that the produce they buy is grown following certain food safety practices.

¹ No current information is available on the relative importance of different marketing channels for produce sales. Research on produce sales in 1997 showed that retail accounted for 48 percent of produce sales, foodservice establishments accounted for 50 percent, and direct-market sales accounted for the rest (Kaufman et al., 2000). In 2017, sales at food and beverage stores totaled \$652 billion, compared to approximately \$619 billion at foodservice and drinking places. So, just over half of the total value of food sold in the United States moved through retail channels (U.S. Census Bureau, 2018). These figures do not account for direct sales to consumers, such as sales through farmers markets or u-pick operations, as the Census Bureau does not track these sales.

The grower would then have to develop a food safety plan and get an independent, third-party auditor to visit the farm to verify that the practices are in place and meet the standard. Because growers and their shippers want to maintain market access, retail requests for third-party audits are often met. While a third-party audit does not guarantee food safety, it assures the buyer that reasonable precautions are being taken.

In 1999, Safeway became the first U.S. grocery chain to require audits from its suppliers of “high risk” fresh produce. Initially, “high risk” meant leaf lettuce. Subsequently, the definition expanded to encompass other items and eventually covered all produce items (Petersen, 2009). Albertsons also began requiring audits in 1999 (Fulmer, 2001). Many other retailers followed. While the third-party food safety audit is widely used by retailers, it is not required by the PR.²

The PR specifically addresses the grower community and does not require anything of retailers. Retailer food safety requirements, however, have shaped the current food safety landscape and will determine the extent to which the PR affects a significant portion of growers. If retailers already demand many of the PR’s food safety practices, their suppliers may face fewer adjustments as the PR is implemented. This report focuses on the retail sector’s food safety requirements for their produce suppliers, how these requirements evolved, if the requirements will change when the PR is implemented, and whether retailers will require more stringent standards from growers than the PR requires.

² A retailer could also have its own food safety standards with its own (company) auditors who verify compliance. This would be considered a second-party audit.

Background: Foodborne Illness Outbreaks, Food Safety Programs, and Third-Party Audits

Foodborne Illness Outbreaks Prompt Development of Food Safety Programs

Food safety programs have often emerged in response to an outbreak of foodborne illness. After an outbreak, retailers realize they have to do something to regain the confidence of the public, as they were likely the point of sale for the implicated commodities. The following outbreaks were particularly important in developing retailers' thinking about food safety.

In 2006, an outbreak linked to California spinach became a major pivot point for food safety in the produce industry (table 1). This was the first time the FDA issued a blanket advisory to consumers not to purchase or consume a particular domestic produce commodity. No spinach was shipped from the primary production region in California until the FDA gave the all-clear 2 weeks later. In response, the California leafy greens industry in 2007 initiated the Leafy Greens Marketing Agreement (LGMA)—a voluntary program that requires participants to implement mandatory food safety practices, with third-party audits provided by California Department of Food and Agriculture inspectors licensed by USDA's Agricultural Marketing Service (Calvin et al., 2017). The LGMA food safety requirements cover the same risk factors as the PR.³ An Arizona counterpart to the California LGMA, the Arizona Leafy Greens Marketing Agreement, also went into effect in 2007.

In the aftermath of this outbreak, some in the produce industry also began advocating for mandatory Federal food safety rules for produce (Calvin, 2007). In addition, some retailers and other buyers began requiring more food safety audits, and some commercial buyers required standards beyond those mandated by the LGMA, which led to concern about an “arms race” in food safety standards, with individual buyers adding specialized requirements (Paggi, 2008).

In 2008, a large-scale foodborne illness outbreak attracted nationwide attention and sparked demand for more food safety regulation. In that outbreak, initially attributed to tomatoes but later linked to Mexican chili peppers, 1,442 people fell ill and 2 may have died from the *Salmonella* infection (CDC, 2008). At the time, the Florida and California tomato industries, separately, had already adopted stronger food safety practices after earlier foodborne illness outbreaks linked to their products.⁴

In 2011, an outbreak linked to Colorado cantaloupe contaminated with *Listeria monocytogenes* was particularly important in motivating food safety efforts because 30 deaths were associated with the outbreak (CDC, 2012a). Another outbreak linked to cantaloupe, this time from Indiana, occurred in 2012 (CDC, 2012b). These cantaloupe outbreaks led to several new grower-organized food safety programs.⁵

These and other foodborne illness outbreaks have prompted numerous actions by both industry and public regulatory bodies; one of the most enduring is the third-party audit.

³ The final Produce Rule comprises the following major sections: personnel qualifications and training; health and hygiene; agricultural water; biological soil amendments; domestic and wild animals; growing, harvesting, packing, and holding activities; and equipment, tools, buildings, and sanitation (a separate section applies to sprout operations). (FDA, 2015a).

⁴ The Florida tomato industry had begun a mandatory food safety program in the fall of 2007 using a State statute to impose standards. In the same year, California growers formed a cooperative that required food safety practices and audits (Calvin, 2013). The cooperative no longer exists.

⁵ In 2012, the California Cantaloupe Advisory Board voted to add food safety requirements to its marketing order, and the Rocky Ford Growers Association and the Eastern Cantaloupe Growers Association require food safety audits for their members.

Table 1.

Food safety timeline: Selected foodborne illness outbreaks and responses to food safety problems, 1995-2018

Year	Foodborne illness outbreak linked to:	Pathogen	Illnesses (deaths)	Food safety actions by industry	Food safety actions by Government
1995	California lettuce	<i>E. coli</i> O157:H7	NA (NA)		
1996	Guatemalan raspberries	<i>Cyclospora</i>	1,465 (0) ¹		
	Unpasteurized apple juice	<i>E. coli</i> O157:H7	66 (1)		
1997	Guatemalan raspberries	<i>Cyclospora</i>	NA (NA)		The White House announces the “Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables”
1998					FDA issues guidance for industry to “Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”
1999				Safeway becomes the first retailer, followed by Albertsons, to require food safety audits	
2000				Global Food Safety Initiative (GFSI) launches	
2002					FDA announces Juice Hazard Analysis Critical Control Point (HACCP) Rule
					USDA, Agricultural Marketing Service introduces Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audits
2003	Mexican green onions (Pennsylvania outbreak)	Hepatitis A	500+ (3)		
2006	California spinach	<i>E. coli</i> O157:H7	204 (3)		
2007				California Leafy Greens Marketing Agreement requires food safety practices	

Continued—

Table 1.

Food safety timeline: Selected foodborne illness outbreaks and responses to food safety problems, 1995-2018—continued

Year	Foodborne illness outbreak linked to:	Pathogen	Illnesses (deaths)	Food safety actions by industry	Food safety actions by Government
2007 (con't)				Arizona Leafy Greens Marketing Agreement requires food safety practices Florida tomato Good Agricultural Practices become mandatory under State law California tomato industry adopts cooperative with food safety requirements	
2008	Mexican chili peppers (tomatoes implicated initially)	<i>Salmonella</i>	1,442 (2)	Wal-Mart is the first U.S. retailer to require a GFSI food safety audit	
2009				United Fresh Produce Association launches the Produce Good Agricultural Practices (GAP) Harmonization Initiative	
2011	Colorado cantaloupe	<i>Listeria monocytogenes</i>	147 (30)		Food Safety Modernization Act becomes law
2012	Indiana cantaloupe	<i>Salmonella</i>	261 (3)	California Cantaloupe Advisory Board adds food safety requirements to its marketing order Rocky Ford Growers Association forms with food safety requirements	
2013				Eastern Cantaloupe Growers Association forms with food safety requirements	
2015					FDA releases final Produce Rule
2018	Arizona romaine lettuce	<i>E. coli O157:H7</i>	210 (5)		Produce Rule comes into effect for largest covered farms

NA = not available. FDA = U.S. Food and Drug Administration.

¹Illnesses are for the United States and Canada combined.

Sources: USDA, Economic Research Service using data from AZ LGMA; Calvin, 2003; Calvin et al., 2004; Calvin, 2007; CDC, 2008; CDC, 2012a; CDC, 2012b.

Third-Party Audit Standards

A variety of third-party audits exist to verify U.S. growers' produce operations meet safety standards.⁶ Some audit standards may be stricter than others.⁷ With the advent of the PR, most auditing bodies are changing their required practices to match those of the PR. Although the PR doesn't mandate third-party audits, retailers rely heavily on them to ensure adherence to food safety standards. Some of the most demanding audit standards will need little change to comply with the PR. For example, the USDA, Agricultural Marketing Service (AMS) LGMA audit standard is already closely aligned (Calvin et al., 2017). Others will have to make more substantial changes.

USDA, AMS has offered food safety audits since 2002. It took FDA's 1998 GAPs guidance document and created the USDA, AMS Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audit program (USDA, AMS, 2018). In 2009, with the proliferation of demands for food safety standards and audits, the United Fresh Produce Association, a large U.S. produce industry organization, launched the Produce Good Agricultural Practices Harmonization Initiative to develop a standard the entire produce industry could accept. In 2011, USDA, AMS began offering the Harmonized GAP Audit, developed from the initiative. It is more demanding than the USDA, AMS basic GAP and GHP audits. Other auditing bodies followed this example. In addition, USDA, AMS conducts audits for industries with commodity-specific food safety programs, such as the California Leafy Greens Marketing Agreement.⁸

In 2000, the Consumer Goods Forum, a nonprofit food industry collaboration initiated by European retailers, launched the Global Food Safety Initiative (GFSI) to "benchmark" or establish equivalency between its standard and other private standards. Currently, GFSI recognizes as equivalent several audit standards frequently used in the U.S. produce industry, including Primus Global Food Safety (Primus GFS), GlobalG.A.P., and Safe Quality Food (SQF).⁹ In theory, if one buyer wanted a Primus GFS and another required an SQF food safety audit, the grower could use one to comply with both requests. In 2008, Walmart was the first U.S. buyer to require all produce suppliers to certify they meet the GFSI audit standard (Wal-Mart, 2008).

Currently, many U.S. growers meet multiple audit standards and have multiple audits on their operation each year. For example, a single grower may need a USDA, AMS audit for one program or buyer (for example the California LGMA or USDA's commodity procurement programs) and a GFSI-equivalent audit for another buyer. Growers would like one audit to serve all purposes, but buyer requirements are not consolidated into a single standard (Calvin et al., 2017). As of early 2019, GFSI could not benchmark a Government audit, which means it could not claim the GFSI audit standard would serve as complete

⁶ Throughout this report, we refer to third-party audits, which are conducted by an entity outside either the buyer or the seller. There are also self-audits and buyer-audits, where the grower or buyer, respectively, is responsible for conducting the audit. We discuss third-party audits because these are the audits that the retailers interviewed have used.

⁷ Audits are the act of ensuring compliance, often through a physical inspection, with a particular standard set forth by the industry, government, or other regulating body. Standards refer to the specific practices, requirements, or documenting procedures required by a regulatory body. Finally, certification, mentioned by many of the retail buyers included in this case study, refers to the documentation that shows a grower has been audited successfully or unsuccessfully. Often when buyers in this report mentioned requiring a third-party audit, they only ever saw the certification of a pass or fail as evidence of compliance with their specified food safety standard. For a more detailed discussion on third-party audits, audit standards, and audit certification, see Calvin et al. (2017).

⁸ USDA, AMS does audits for many of the grower-organized food safety programs: the California LGMA, Arizona LGMA, Tomato Food Safety Audit Protocol, California cantaloupe food safety program, and the Mushroom GAP audit program.

⁹ Use of a private firm name does not imply any USDA endorsement, nor is this list exhaustive.

evidence of compliance with the PR requirements. Because the PR does not require a third-party audit, there is no recognized auditing scheme that fully guarantees compliance with the PR. However, GFSI now has a “technical equivalency” program for Government food safety standards. It is not the full GFSI benchmarking done for private food safety programs, but it recognizes that the PR food safety standard is nearly equivalent to the food safety requirements of GFSI (2017). As stated on the GFSI website, “being GFSI certified will take you a long way down the road to FSMA compliance” (GFSI, 2017b). USDA, AMS submitted an application to GFSI for technical equivalency for its new Harmonized GAP Plus+ audit (more rigorous than the Harmonized GAP audit) and hopes to have it judged to be technically equivalent to GFSI soon (Petersen, 2018). Consolidation and harmonization efforts are all aimed at reducing the number of audits needed by a grower.

Produce Grower Food Safety Practices Surveys, conducted in 2015 and 2016 by USDA’s Economic Research Service and National Agricultural Statistics Service, showed an average of 30 percent of the growers who are required to comply with the PR had a third-party audit within the prior 2 years. This ranged from 29 percent of smaller farms (average sales over 3 years equal to or greater than \$25,000 in produce sales but less than \$500,000 in agricultural sales annually) to 63 percent of very large farms (average produce sales over 3 years of more than \$5 million) (Astill et al., 2018). While it is not possible to attribute all of these audits to the influence of retailers, research has found evidence of an impact.¹⁰

Because third-party audits have helped shape the modern food safety landscape, and because retailers have long required third-party audits to access retail markets, it is crucial to understand the role of retailers in food safety.

Retailers’ Role in Food Safety

In 1999, research suggested private-sector incentives were becoming a driving force behind the adoption of food safety standards (Henson and Caswell). Since then, the literature on retail requirements and food safety has reached a consensus, largely through small-scale surveys conducted by phone or by mail for cost reasons, that food producers implement food safety standards to maintain or gain access to broader retail markets (Hatanaka et al., 2005; Fulponi, 2006; Fouayzi et al., 2006; and Mensah and Julien, 2011). Providing safer food to the final consumer is another reason cited for adopting food safety protocols, a rationale nearly always expressed in tandem with claims about retail buyer requirements or marketability (Fouayzi et al., 2006). The costs of adopting food safety practices can mean some growers will not be able to market through retailers demanding audits (Hatanaka et al., 2005). Some studies argue that private food safety institutions led by retailers participating across international borders are the opposite of domestic regulations, which hamper trade across borders (Henson, 2008). Rather, because these corporations and their markets span borders, the push to harmonize international recognition of standards helps to facilitate the movement of goods and ultimately improves market penetration.

The interviews conducted for this study largely follow the established pattern of the literature: phone interviews with a relatively small but diverse group of retailers within the U.S. fresh produce supply chain. This study’s primary addition to the existing research is its attempt to understand how retailers, as drivers of private food safety standards, are planning to adapt to the PR. This study is the second in a series on food safety in the produce industry. The first, by Astill et al. (2018), details results of a survey of grower food safety practices; this report gives background on why these practices have been adopted.

¹⁰ Lichtenberg and Tselepidakis (2016) found evidence that shares of produce sold to grocery/retail and to restaurants are positively correlated with the probability of a grower testing water, soil amendments, or product samples.

Retailer Interviews

To develop a case study of retailers' food safety programs as they relate to produce growers and the fresh produce industry, researchers at Cornell University conducted interviews for USDA's Economic Research Service (ERS) between December 2016 and February 2017 (see box, "Sample Design").¹¹ The researchers contacted nine retailers by phone to learn about their current food safety requirements for produce, how the requirements evolved, and how they might change with implementation of the PR. Given the various formats, sizes, and geographic distribution of the companies interviewed and the range of their responses regarding food safety programs and strategies, we believe the results reflect many of the policies of U.S. supermarket companies.

Sample Design

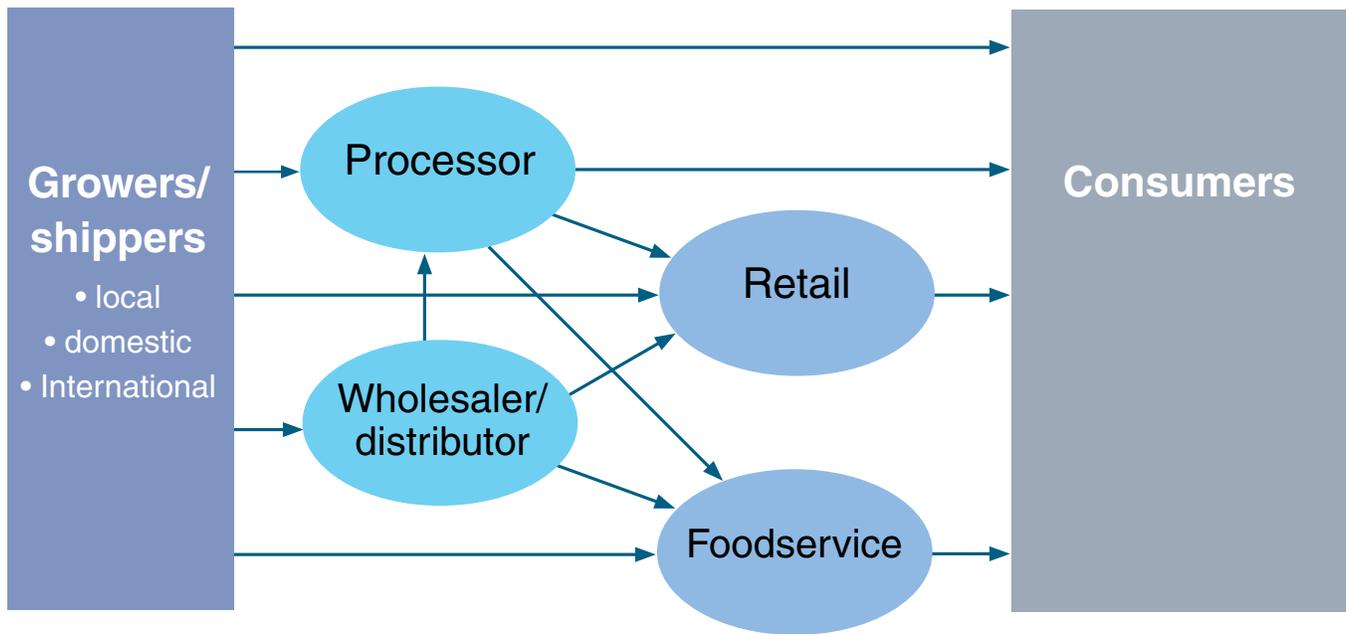
Retailers were chosen so at least one store from a participating company was located in each of the 48 contiguous States of the United States. The nine participating companies range from large, multi-region chains to independently owned stores. Store format types include supermarkets, supercenters, wholesale membership clubs, and independent supermarkets. While the companies represent a cross section of the retail food industry and reported a range of food safety programs and strategies, the sample is too limited to statistically represent the industry.

Cornell University researchers interviewed company executives whose primary work involved fresh produce procurement and/or food safety regulatory compliance. Our goal was to interview the person most knowledgeable about the company's food safety policies and the food safety behaviors of its suppliers. We found that no one person in the companies knew all of the information of interest to the study.

To maintain consistency in conversations, interviewers used an interview guide (see Appendix), developed jointly by researchers at Cornell and USDA's Economic Research Service. The guide was designed to elicit information on retailers' current food safety requirements for produce, how the requirements have evolved, and how they might change with implementation of the Food Safety Modernization Act's Produce Rule. Respondents did not receive any incentives to participate.

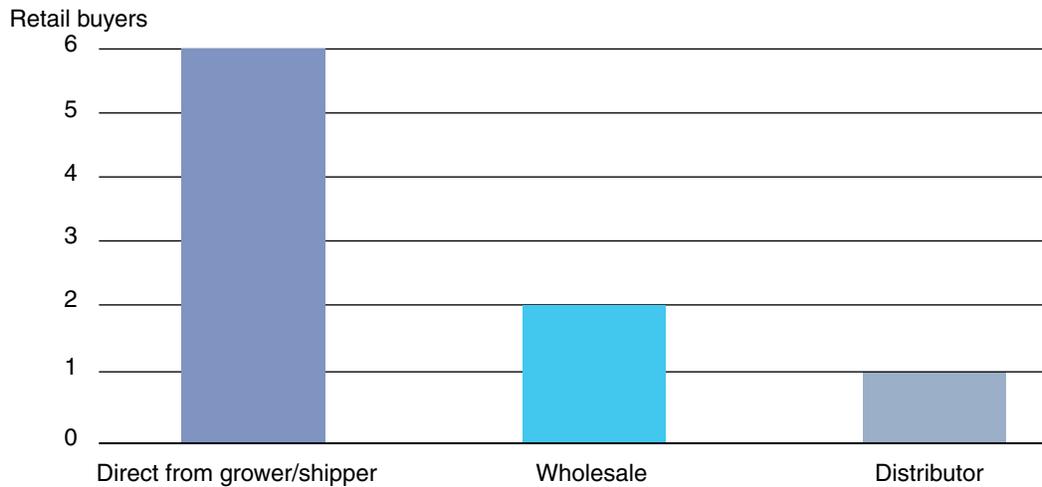
¹¹ While both ERS economists and Cornell University researchers were involved in developing the general questions used in the interviews, Cornell researchers conducted the interviews and are the only ones who know the identities of the retailers.

Figure 1.
Marketing chain for produce



Source: Conceptual rendering developed by USDA, Economic Research Service and Cornell University.

Figure 2.
Sources of retail produce for participating retailers



Source: USDA, Economic Research Service and Cornell University.

The distribution chain for fresh produce to the consumer can be complicated (fig. 1). It involves a number of participants, each of which may have its own food safety and other buying requirements. However, as with the food retail industry as a whole, our sample has largely moved to a more direct line of purchasing, getting product directly from the grower or primary supplier (fig. 2).

In this case study, six of the nine retailers are self-distributing; that is, the companies have their own buying offices and distribution centers, and they purchase the majority of their produce directly from grower-shippers, operations that both grow and distribute their own produce, and shippers, who ship but do not grow. Two of the retailers purchase almost all of their produce from grocery wholesalers, who buy large quantities of fresh produce and sell to intermediaries such as retail grocers. One retailer purchases most of its produce from a large produce distributor. Distributors are responsible for handling the purchasing and transportation logistics for retailers; the distributor receives the purchase orders from the retailer, who has already negotiated purchase agreements with the shippers. Different types of purchasing structures can have an impact on the food safety practices required.

Produce represents an average of 10 percent of total store sales for these retail companies.¹² The number of produce suppliers ranges from around 50 to well over 1,000 per company.¹³ Among the suppliers, the reported number of “local” suppliers ranges from about 30 to 165 (table 2).

Table 2.

Characteristics of retail firms interviewed

	Average	Number of firms with response
Percent of total sales from produce	10	9
Number of produce items (SKUs)	750	7
Number of produce vendors	200	9
Number of local* produce vendors	40	8

Note: Averages reflect the wide range of responses characteristic of the diverse sample of nine firms interviewed for this study. Averages are presented for illustrative purposes only and not to suggest representativeness. * Retailers’ definitions of “local” vary from “within the same State” to “within a radius of” a defined number of hours or miles. Therefore, the number of “local” produce vendors varies dramatically by geography, with companies on the west coast and in the South having higher “local” produce than those in the north-central or northeast regions. SKUs = stock keeping units.

Source: USDA, Economic Research Service.

Retailers’ definitions of “local” vary from within the same State to within a radius of a defined number of hours or miles. Likewise, the “local” share of produce sales may vary dramatically by geography. One retailer based in California reported, “Most produce suppliers are local in California.” Imported produce averages about 27 percent of annual produce sales, according to participants, with the share of imports varying with the change of seasons in the United States (fig. 3).¹⁴

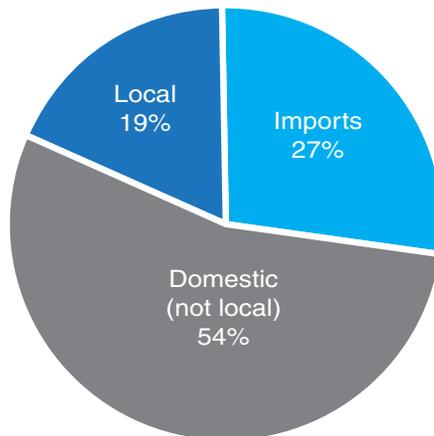
¹² This is close to the 2016 national average of 12 percent reported by the Food Marketing Institute (Food Marketing Institute, 2017).

¹³ For some commodities, a retailer might buy from several suppliers as the seasons and production locations change. On the other hand, many large grower-shippers provide the commodity from several U.S. regions or countries to provide a year-round supply, which reduces the effort needed by the retailer.

¹⁴ Although the respondents were not asked directly about FSMA’s Foreign Supplier Verification Program, one reported that it was uncertain about how to interpret the language of the program, although the respondent’s company was not the importer of record. Other respondents also mentioned they were uncertain about who is considered the importer of record.

Figure 3.

Local, domestic, and international sources of produce for participating retailers



Source: USDA, Economic Research Service and Cornell University.

Similarly, the definition of a “small” supplier may vary among retailers. Although the PR defines small produce growers as those making more than \$25,000 but less than \$250,000 in annual produce revenue, we do not make that distinction in this report. During conversations with retailers, researchers asked about the impact on and flexibility afforded to “small” suppliers, but left the term largely to the interpretation of the retailer.¹⁵

¹⁵ If the retailer asked for clarification of the term “small,” the PR definition was provided, but this was not normally requested.

Interview Results

Based on the conversations with retailers about their food safety requirements, five themes emerged: demand for third-party audits has increased; audit standards have evolved as the science and understanding of foodborne illness have grown; retailers are more sensitive to commodities with a history of foodborne illness and are more likely to require audits in those cases; retailers largely require some kind of food safety assurances from their producers regardless of size, but they offer some flexibility, especially for smaller local producers; and retailers do not anticipate that most of their suppliers will incur excessive additional costs to implement the PR requirements, but they acknowledge they may lose some suppliers who are unable to comply.

Audit Requirements Over Time

All of the retailers interviewed have food safety requirements for suppliers and require food safety audits. All reported their food safety requirements have evolved as major food safety incidents raised awareness of a food safety risk (table 1). The majority began requiring food safety audits in the last 5 to 8 years, following high-profile foodborne illness outbreaks such as the 2008 outbreak linked to chili peppers and the 2011 and 2012 outbreaks linked to cantaloupe. However, three retailers initiated food safety audit requirements earlier: one in response to the 2006 outbreak linked to spinach, and the other two even earlier. The two earliest adopters did not indicate their motivation. Most said food safety programs were initiated simultaneously for domestic and imported products. All said audits are critical tools to ensure food safety. Although audits are not required under the PR, none of the retailers in this case study was considering reducing the use of audits.

Audit Requirements by Commodity

After the 2006 foodborne illness outbreak linked to spinach, the retail industry focused on improving food safety for leafy greens and other “high risk” items such as cantaloupe, berries, tomatoes, sprouts, green onions, and bagged salads.¹⁶ Most retailers interviewed demand food safety audits for all commodities; some have even more demanding standards for commodities they perceive as high risk, such as leafy greens and cantaloupes. The PR does not cover produce rarely consumed raw—such as potatoes and beets (see box, “Growers and Commodities Not Covered by the Produce Rule”). But most of the interviewed retailers include them in their food safety requirements.

With a heightened awareness of food safety, some of the interviewed retailers will not buy certain products with a history of foodborne illness outbreaks. Two said they have stopped selling sprouts because of continuing outbreaks associated with this product.¹⁷ Some said they will not sell particular products imported from countries that have had notable food safety outbreaks or spotty enforcement of regulatory standards.¹⁸

¹⁶ In 2015, the FDA produced a qualitative assessment of risk for produce in which it ranks commodities as having a higher or lower risk of causing foodborne illness (FDA, 2015c).

¹⁷ According to the CDC, 57 outbreaks associated with 1,891 illnesses, 209 hospitalizations, and 5 deaths occurred between 1998 and 2017 where “sprouts” were implicated as a food/ingredient (CDC, 2016).

¹⁸ For example, after repeated outbreaks in the United States linked to raspberries from Guatemala beginning in the mid-1990s, retailers stopped buying raspberries from Guatemala and began buying them from Mexico instead (Calvin, 2003).

Audit Requirements by Size of Producer

Small growers can find the upfront and annual costs of complying with a food safety audit challenging. Since that hurdle will be significantly greater with the added documentation and increased vigilance required by the PR, retailers were asked if they hold smaller growers to the same audit standard as they do large growers. The PR does not require smaller growers and those who sell through particular marketing channels to comply (see box, “Growers and Commodities Not Covered by the Produce Rule”).

Only one retailer reported it does not require audits from its small suppliers. Two-thirds of the retailers accept a variety of certification standards.¹⁹ Five of the respondents require the same standards be met by large and small suppliers. The other four hold larger suppliers to higher standards than smaller suppliers. For example, one requires large suppliers to comply with an audit that meets GFSI standards, but smaller local suppliers may comply with a USDA, AMS Harmonized GAP audit. The only exception is if these smaller growers supply high-risk commodities or commodities sold under the retailer’s private label. In these cases, the smaller growers also must certify that they comply with GFSI’s more stringent standards.

Three independently owned retailers purchase most of their produce from a wholesaler or distributor and rely on these companies to secure food safety audits from suppliers. These retailers may not have the specialized expertise to evaluate or propose a food safety program. In general, wholesalers and distributors use the same food safety programs as retailers. For produce not sourced from a wholesaler or distributor, these retailers rely on additional, usually local, suppliers that they require to have USDA, AMS GAP-GHP audits. One retailer that purchases most of its produce through a wholesaler reported: “We use our wholesaler as our supplier for fresh produce, so we have not had to do a lot to get ready for the FSMA regulations. We are, however, working with many local suppliers. We have to make sure they are in compliance by helping them get in touch with the Department of Agriculture in the State they are in.” Another reported it will rely on its wholesaler on all matters involving the FSMA implementation.

Growers and Commodities Not Covered by the Produce Rule

The Food Safety Modernization Act’s Produce Rule (PR) does not cover all growers or all fresh market commodities, and it offers a qualified exemption for smaller growers selling locally. The groups of growers listed below are not required to comply with the PR. This is not an exhaustive list. For a full list of exemptions and coverage details, see the language in the rule (FDA, 2015b). According to the regulation:

- Farms with \$25,000 or less in average produce sales over the previous 3-year period are not covered.
- Farms can earn a qualified exemption if the farm’s previous 3-year average food sales are less than \$500,000 and sales to “qualified end users” are greater than all other sales. Qualified end users include: (a) the consumers of the food (not a business) and (b) a restaurant or retail store located in the same State or reservation as the farm or within 275 miles of the farm. These growers have to comply only with minimal labeling requirements and maintain records to prove they meet these requirements.
- Fresh market commodities rarely consumed raw (potatoes, beets, etc.) are not covered.

¹⁹ Such as GFSI; USDA, AMS GAP-GHP; USDA, AMS Harmonized GAP; GlobalG.A.P.; and SQF.

Table 3.

Comparison of food safety practices required by the Food Safety Modernization Act (FSMA) and by retailers

Food safety practice	Required by FSMA	Required by retailers	Likely to change on implementation of the FSMA's Produce Rule
Written food safety plan	No	Yes	No
Third-party audit	No	Yes	No
Final product testing	No	No	No
Food safety training	Yes	Yes	No
Water testing	Yes	Yes	Yes
Monitor for animal intrusion	Yes	Yes	No
Cleaning of equipment and tools	Yes	Yes	No
Recordkeeping	Yes	Yes	Yes
Exemption for small or local operations	Yes	No	No

Note: Requirements are from published FSMA requirements and published third-party audit criteria. In this study, the nine participating retailers were not asked about specific FSMA requirements or how they expected their suppliers to change behavior in response to implementation of the Produce Rule.

Source: USDA, Economic Research Service using data from Astill et al., 2018; Calvin et al., 2017; FDA, 2015a.

Some of the interviewed retailers said it is difficult to enforce food safety requirements for smaller producers in every case. Some said they allow store managers leeway in buying from small local growers. Although growers are supposed to be in the retailers' corporate vendor system and comply with food safety requirements, managers sometimes have the flexibility to bypass that system.

Transition to the PR and Impact on Produce Growers

At the time of the interviews, the PR regulations differed from many existing food safety standards required by retailers, especially with regard to water testing and recordkeeping (table 3).

Most retailers interviewed were unable to estimate how many of their suppliers were already in compliance with the PR standards. This is not surprising since, at the time of the interviews, the January 2018 deadline for full PR compliance for the largest growers was still a year away; smaller growers have later deadlines. The interviewed retailers said they think most growers will have to add monitoring, management, and some recordkeeping practices to comply with the stricter standards for water quality, which will require investment in staff, equipment, or systems. Because some growers will need to change food safety practices to comply with the PR, the retailers expect some of their suppliers will be unable to meet the PR standards and will be dropped. This was viewed as a relatively minor risk, not significantly affecting the retailer's overall supply chain. Four reported having lost suppliers in the past that either could not afford to, or chose not to, comply with the retailer's food safety demands. Such suppliers tended to be small growers who face increased fixed costs spread over smaller acreage. Most interviewed retailers have not offered financial assistance to smaller suppliers that cannot afford to meet their food safety requirements and do not plan to do so. Only two offer direct financial assistance to

smaller local suppliers to improve food safety programs, and only one pays a higher price for the product to compensate for higher food safety costs.

Interviewed retailers said they did not anticipate requiring standards higher than those required under the FSMA. None required any addendums or riders to third-party audits for additional food safety practices, nor were they planning to do so. Asked about the benefits of the PR, most retailers said the new rules and processes will not significantly improve the safety of the produce they buy and sell. While the PR does not specifically require traceback capability, retailers said any additional required recordkeeping could be valuable in tracing the source of problems, should they arise.

Although the PR exempts certain types and sizes of growers, all but one retailer interviewed require food safety audits from all suppliers. In this case, they demand more than the PR requires. It is not clear, however, if all small growers will have to have an audit using standards that follow the PR. At the time of the interviews, some of the retailers allowed small growers to use a less demanding food safety audit. That may continue for growers that are not required to comply with the PR. On the other hand, some retailers said they will require PR-compliant standards for all their suppliers.²⁰ One reported: “We require them to be compliant anyway.” Said another: “Although local (suppliers) don’t follow as strict certifications, I can’t think of anyone without. It is a leading point in any conversation. Most vendors will lead with information on their certification.”

Interviewed retailers believed that although there would be some, likely minimal, changes to their suppliers' food safety practices, the implementation of the PR would not drastically affect the growers selling into larger and national grocery chains. Instead the retailers interviewed saw the PR most significantly affecting those growers outside of their supply chains, such as those selling direct to consumers or through non-traditional retailers. It is these growers, who may not be as familiar with food safety practices, or have never experienced a food safety audit, who were viewed as having the most to do to come into compliance with the PR.

²⁰ Retailers report that interpreting the complex FSMA documents is a major challenge in implementing standards and practices. The wording of some sections can be interpreted in various ways. In some cases where the language is not clear, retailers are erring on the side of caution by, for example, keeping duplicate records of import transactions even though the retailer is not the importer of record.

Conclusions

Retail demands for food safety have grown as the risks and economic impacts of foodborne illness outbreaks have become more obvious. Of the nine retailers we interviewed, all but one require food safety practice certification from all growers, including small growers. All require audits for all fresh fruits and vegetables, including commodities exempt from the Food Safety Modernization Act's Produce Rule (PR). The interviewees suggested their grower requirements align with the PR, and they do not intend to demand plans, programs, or standards beyond those described in the PR or that they currently require.

The PR recommends but does not require a third-party food safety audit. The retailers interviewed already demand these audits from their suppliers, indicating they are a critical risk management tool. The interviews suggest retailers are unlikely to drop their third-party audit requirements because they are not required under the PR.

A minority of retailers indicated they may allow smaller growers to use a less demanding third-party audit than required for their larger suppliers. The retailers also indicated they may require more demanding food safety audits for commodities or products they view as posing a greater risk of potential microbial contamination based on a history of foodborne illness outbreaks.

The PR sets a new minimum standard for food safety practices. Most retailers interviewed think current audit requirements will change to meet the PR requirements, particularly with respect to water and recordkeeping. They anticipate they may lose some suppliers that either cannot afford or are not willing to comply with new rules.

The interviewed retailers do not view the PR as a new frontier for safety practices. Instead, most believe their large suppliers are largely in compliance with the regulation, apart from having to make some relatively minor adjustments. Growers who are large enough to be covered by the PR but not large enough to supply big retailers may need to make more adjustments to comply with the new food safety regime. Accordingly, the retailers saw the PR as raising the floor on food safety. Although they said some suppliers might fall out of their supply chains, most retailers thought this would not disrupt or alter their supply of fresh produce in any significant way. In addition, they did not believe that implementation of the PR will drastically affect their growers. Rather, they expected produce growers outside of their supply chains to be the most affected.

Although only nine retailers were interviewed, they expressed similar responses and concerns, regardless of their size, ownership type, location, or format. They showed a common understanding of the FSMA regulations, and they recognized the increased water and recordkeeping requirements as a significant burden. This consistency indicates these responses reflect adjustments to food safety practices underway in the industry.

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Appendix—Interview Guide

Company demographics

What percent of your company's sales is from produce?	
How many produce items, or SKUs, do you carry in your produce department throughout the year?	
Number of total produce vendors	
Number "local"	
Number exempt from FSMA	
Percent of produce imported	

Current food safety requirements for suppliers

Do you require all of your produce suppliers to have a food safety program? If no, what types are exempt?	Yes No	
Do you have the same requirements for all suppliers? If no, which are different?	Yes No For example, local, small/exempt, wholesaler, foreign, etc.	
Do you have the same requirements for all commodities? How do you determine which suppliers or which commodities will have different requirements?	Organic vs. conventional? Products typically consumed raw vs. cooked? Commodities involved in recent outbreaks?	
Describe the food safety program for the following supplier types: "Customary or average" Small/local Wholesaler Foreign	Describe the standards, audits, or certifications that you require. For instance, Primus, SQF, GlobalG.A.P., USDA GAP, your own retail standard, other	Any addendum of your own?

Continued—

Current food safety requirements for suppliers—continued

When did you start requiring food safety programs and audits?		
Did you start requiring audits for domestic and imported at the same time?		
How do FSMA guidelines align with food safety programs you currently require? For example, are your requirements the same, more, less?		
Are there any products you won't accept from a foreign source? What are they? And why not?		
Have you lost suppliers in the last 2-3 years who could not, or chose not to, comply with your food safety requirements? If yes, could you describe which types of suppliers?	Yes No	
Have you provided financial support for growers to adopt food safety practices or have you paid for audits to keep them as suppliers? What type of support have you provided? What type of growers have you supported?		

Food safety requirements compared to the Food Safety Modernization Act

Do you know about what percent of your suppliers are not yet in compliance with the FSMA? What type of supplier?
Will FSMA standards be enough, or will you require additional standards? If more, what will you require? For all commodities or just some?
For those suppliers that are exempt or qualified exempt under FSMA, will you require food safety audits anyway? If so, what audits or standards will you require?
Once FSMA is fully implemented, do you expect to lose any suppliers who cannot, or who choose not to, comply with your requirements? If yes, could you describe what kind of suppliers these might be?
Will you provide financial support to help suppliers comply?

Do you have additional comments about your food safety requirements or about FSMA to share with us?

Will FSMA benefit your company?

Will there be winners and losers in the supply chain?

Will consumers benefit?

Note: SKU = stock keeping unit. FSMA = Food Safety Modernization Act. SQF = Safe Quality Food. GAP = Good Agricultural Practices.

Supplemental materials for interviews

a. Exempt or qualified exempt from FSMA?

i. Exempt. Interviewers will prompt with definition of exempt if necessary: These are farms with an annual average value of produce sold of \$25,000 or less or that sell products that are exempt from FSMA: 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; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; water chestnuts; and food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflowerseed).

ii. Qualified exempt. Interviewers will prompt with definition of qualified exempt: The farm must have food sales averaging less than \$500,000 per year during the previous 3 years; and the farm's sales to qualified end users must exceed sales to all others combined during the previous 3 years. A qualified end user is either (a) the consumer of the food or (b) a restaurant or retail food establishment located in the same State or the same Indian reservation as the farm or not more than 275 miles away.