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Estimated Costs for Fruit and Vegetable Producers To Comply With the Food Safety Modernization Act's Produce Rule

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Abstract

Under the Food Safety Modernization Act of 2011, the U.S. Food and Drug Administration started to implement its Produce Rule in phases beginning in 2018. Implementation of the rule will increase costs for farms supplying almost all fresh produce sold in the United States. This study estimates farm-level costs to comply with the rule by commodity, State, and farm size. Across commodities and States, differences in costs are driven by differences in farm size and range from 0.3 percent of annual produce sales for the largest farms to 6.8 percent for the smallest.

Keywords: food policy, food safety, Food Safety Modernization Act, FSMA, produce markets, regulation.

Acknowledgments

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What Is the Issue?

In an effort to improve food safety by reducing foodborne illnesses, the Food Safety Modernization Act of 2011 (FSMA) empowered the U.S. Food and Drug Administration (FDA) to impose new regulatory requirements on food producers and handlers, to expand require-ments for and inspections of food imports, and to issue mandatory recalls of food. As a result, FDA gained expanded authority to regulate fresh-produce production practices at the farm level. The FSMA Produce Rule will be implemented in phases beginning in 2018 and will affect farms supplying almost all fresh produce sold in the United States.

As part of the rule-making process, FDA estimated the cost of compliance with the Produce Rule for a few broad categories of farms distinguished by annual produce sales value and exemption status. In its analysis, FDA estimated the total costs of compliance to be $368 million for domestic farms (annualized over 10 years, using a 7-percent discount rate) but did not estimate the costs by commodities or regions. Using those original FDA estimates, this study provides estimates of the cost of compliance with the Produce Rule by commodity, State, and farm size (based on sales). The findings of the study have implications for understanding future competitiveness of smaller farms and markets for locally grown fruits and vegetables and enable researchers to characterize effects of FSMA on retail prices, by commodity.

What Did the Study Find?

The many fixed costs associated with the administrative and personnel components and the food safety process components of complying with the Produce Rule cause compliance costs to be higher as a share of revenue for smaller farms. For this reason, fruit and vegetables produced on larger farms are estimated to have smaller compliance costs than those produced primarily on small farms. Findings on the annual costs of compliance with the Produce Rule upon full implementation of the rule in 2022 include the following:

- Farms with annual produce sales over $3,450,000 account for 58.6 percent of U.S. farm produce sales and are estimated to incur annual costs of compliance of about 0.3 percent of the value of their produce sales. Farms with annual produce sales between $500,000 and $700,000 are estimated to incur annual costs of compliance of about 4.2 percent. Small farms (annual sales between $250,000 and $500,000) and very small farms (annual sales between $25,000 and $250,000) are estimated to incur annual costs of 6.0 percent and 6.8 percent, respectively.

- Very small farms that qualify for a partial exemption from the rule are estimated to incur annual costs of around 2.4 percent of the value of their produce sales, compared with 6.8 percent for nonexempt farms of the same size.

- The annual costs of compliance with the Produce Rule are estimated to add about 0.3 percent to the farm cost of producing romaine lettuce (lowest among vegetables considered in this study) and 3.0 percent to the farm cost of producing snap beans (highest among vegetables).

- The annual costs of compliance with the Produce Rule are estimated to add about 0.7 percent to the farm cost of honeydew (lowest among fruits considered in this study). Among fruits primarily grown domestically for U.S. consumption, the highest farm cost is estimated at 3.0 percent for pears. These differences in cost of compliance across commodities reflect differences in farm sizes; fully regulated farms that grow honeydew tend to have much larger value of sales than fully regulated farms that grow pears.

- Differences in estimated cost of compliance, by State and county, depend on the average value of sales for farms subject to the FSMA Produce Rule in each locality. Fully regulated farms in Arizona tend to be quite large; on average, farms in Arizona that are subject to the FSMA Produce Rule are estimated to have the lowest annual cost of compliance among all States, at 0.6 percent of produce sales revenue. Farms in nine States with smaller produce-growing farms (Vermont, Arkansas, Minnesota, Kentucky, Mississippi, Iowa, Alabama, South Dakota, and Alaska) are estimated to have average compliance costs of 3.0 percent or higher.

- Our estimates of compliance costs assume that no farms are already in compliance prior to the enactment of the Produce Rule, thereby representing upper bounds on actual compliance costs. If large shares of farms were already in compliance prior to implementation of the rule, then actual compliance costs will be below our estimates.

How Was the Study Conducted?

This study drew on the FDA's published estimates of the 10-year cost of complying with the Produce Rule to develop a function that relates each farm's produce sales to its cost of complying with the rule. Using data from the 2012 Census of Agriculture, researchers first computed estimates of the cost of compliance for regulated farms falling within different farm size categories, with varying implementation timelines and possible exemptions over the 2016 to 2022 period. They then calculated the average estimated cost of compliance by county and State for different farm sales categories and by fresh-produce commodity.

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Introduction

Passage of the Food Safety Modernization Act (FSMA) in 2011 marked the most comprehensive legislative change in the U.S. Food and Drug Administration's (FDA) authority to regulate food since the 1930s (Johnson, 2011; Johnson, 2014; Ribera and Knutson, 2011). The law empowers the FDA to impose new regulatory requirements on food producers and handlers, to expand requirements for and inspections of imports, and to issue mandatory recalls of food. This study examines the implications of the FSMA Produce Rule regulating fresh-produce production practices and estimates the costs of compliance at the farm level by State and across commodities.

Published in November 2015, the Final Produce Rule (FDA, 2015a) mandates certain on-farm practices related to the safe production of fresh produce. The rule's focus on raw agricultural commodities is comprehensive in terms of the number of items covered. While farms producing foods deemed to be rarely consumed raw (e.g., asparagus, beets, and sweet corn) are exempted, most farms producing fruits and vegetables marketed in a fresh state must meet the rule's specific production practice requirements beginning in January 2018.[1]

As part of the rule-making process, FDA is required to estimate and publish within a Regulatory Impact Analysis (RIA) the total expected costs (and benefits) of each of its major rules under FSMA (the Produce Rule is one of several). For the Produce Rule, FDA (2015b) used data from USDA's 2012 Census of Agriculture to estimate the number of regulated farms in each of three size categories based on annual produce sales: $25,000 to $249,999 (very small); $250,000 to $499,999 (small); and $500,000 and above (large). Farms with annual sales below the minimum threshold for very small farms are exempt from the Produce Rule. Then, FDA estimated the costs of compliance for an average farm within each of these three categories and aggregated costs across farms to estimate the total national cost of the regulation. FDA's estimates reveal that the cost of compliance with FSMA, as a share of a farm's total produce sales, is larger for smaller farms because of the many fixed costs associated with the administrative and personnel components of the regulation and with the food safety process components.

This study uses restricted-access data from the 2012 Census of Agriculture to simulate a fuller distribution of the expected costs of compliance with the FSMA Produce Rule than the FDA does in its RIA. While most produce is grown on large farms, the distribution of farm sizes differs across regions and crops. We leverage data on the distribution of farm size by crop to convert the FDA's estimate of the cost of compliance for a generic farm to a commodity-specific cost estimate, allowing for a more comprehensive analysis of the potential effects of FSMA on produce markets.

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[1]As we discuss further below, large farms with annual food sales of more than $500,000 have been required to comply with the FSMA Produce Rule since January 26, 2018. Smaller farms are allowed to delay compliance for 1 or 2 years, depending on their value of sales. Note that growers of sprouts from beans and seeds had an earlier 2017 phase-in of production practices.

Background

Overview of U.S. foodborne illness outbreaks and food safety regulation

Federal involvement in food safety regulation emerged in 1906 with USDA and FDA, respectively, gaining the authority to oversee meatpacking with the Federal Meat Inspection Act and foods, drugs, medicines, and liquors with the Pure Food and Drug Act. Later legislation[2] expanded USDA's authority to encompass poultry, egg, and dairy inspections and gave the FDA authority over product adulteration and misbranding, safe tolerance levels for poisonous substances, standards related to ingredient identity and quality, and factory inspections.

Aside from the legislative process, the rule-making authority of the relevant agencies enforcing existing laws allows them to issue new regulations consistent with their legal mandate as new information becomes apparent. Two notable examples involve decisions by USDA's Food Safety and Inspection Service (FSIS) to declare the pathogen *E. coli* O157:H7 (a specific serotype of the *E. coli* bacterium that produces the Shiga toxin) an adulterant in 1994 and to declare six other serotypes of *E. coli* that also produce the toxin to be adulterants in 2011. These decisions are often associated with contemporaneous outbreaks of foodborne illness. The first stemmed from a large outbreak associated with ground beef sold by the Jack in the Box hamburger chain in the Pacific Northwest in 1993; the second arose following highly publicized deaths associated with ground beef consumption in 2009 (Moss, 2009a; Moss, 2009b; Moss, 2009c). Shortly after the first outbreak, in 1996, FSIS promulgated the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems rule, which required meat producers to systematically monitor and reevaluate microbiological contamination controls on production lines.

In addition to FSIS and FDA actions, USDA's Agricultural Marketing Service (AMS) has facilitated food safety initiatives undertaken by industry groups through marketing orders and agreements to enforce product standards (see box "Food Safety Provisions of AMS and State Marketing Orders and Agreements"). Private and collective adoption of food safety standards by both buyers and sellers has helped drive changes in norms surrounding the provision of food safety (Bovay and Sumner, 2017; Winfree and McCluskey, 2005; Pouliot and Sumner, 2012).[3]

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[2]Specific legislation includes the Federal Food, Drug, and Cosmetic Act of 1938, the Poultry Products Inspection Act of 1957, the Wholesome Meat Act of 1967, the Wholesome Poultry Act of 1968, and the Egg Products Inspection Act in 1970.

[3]For perspectives on exporting food from developing countries in the presence of buyer standards, see Unnevehr (2000), Martinez and Poole (2004), and Schuster and Maertens (2013).

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Food Safety Provisions of AMS and State Marketing Orders and Agreements

The Agricultural Adjustment Act of 1933 empowered the U.S. Secretary of Agriculture, through the Agricultural Marketing Agreement Act of 1937 (AMAA), to authorize the use of marketing orders and agreements at the Federal level to allow growers of a particular commodity to set rules for marketing their products. State law can allow similar authority to create marketing orders and agreements at the local level. Both marketing orders and agreements are initiated by industry to help provide stable markets for dairy products, fruits, vegetables, and specialty crops. Under a marketing agreement, only handlers who sign onto the agreement are bound by its terms with regard to production or marketing restrictions. Marketing orders can only be enacted after formal rule-making conducted by USDA and the approval of affected producers. With marketing orders, all handlers within a defined geographic area are bound by the terms of the order. These marketing orders are self-governed and self-financed by relevant industry groups. AMS provides oversight to ensure that each program operates according to the AMAA and the Federal marketing order.

Marketing orders can have provisions that (1) require grading and inspection services to meet minimum grade levels; (2) standardize packaging and labeling of containers; (3) sponsor production research projects; (4) create market research and product promotion activities; and (5) increase or decrease the amount of product allowed into commercial channels during periods of exceedingly high or low volume. With limited authority to regulate food safety characteristics as food quality factors, AMS marketing orders are the product of industry initiatives to set and maintain standards. Recent instances of industry groups using marketing orders to address food safety concerns are increasing. The almond marketing order has funded millions of dollars in research on almond quality, food safety, and nutrition. The pistachio industry sets quality standards that require, among other things, testing for aflatoxin, a cancer-causing mold found in many nuts and grains. The hazelnut industry is working to amend the marketing order to add authority to regulate quality for the purpose of pathogen reduction. Though not a marketing order, AMS also ensures that peanuts marketed in the United States are free of aflatoxin. At the State level, the Leafy Greens Marketing Agreement (LGMA) was developed first in California and later Arizona to create a system of food safety practices and audits for 14 leafy greens products following the highly disruptive outbreak of *E. coli* in California spinach in 2006 (Arnade et al., 2009, Calvin et al., 2017).

The Food Safety Modernization Act

FSMA represents the most substantial legislative expansion of FDA regulatory authority since the 1930s (Johnson, 2011). Like previous legislation addressing food safety, FSMA was enacted in the context of changes in the industrial structure of the food industry, including trade liberalization, enhanced economies of scale in production and retailing leading to larger farm sizes, and improvements in shipping technology. These factors increased the distance that food travels before reaching consumers, substantially increasing the share of fruits and vegetables consumed fresh rather than preserved (fig. 1).

As with regulations issued by Federal agencies, the expansion of legislative authority over food safety has often been a reaction to recent food safety events or outbreaks of foodborne illness. Prior to the passage of FSMA in 2010, several high-profile incidents heightened concerns regarding food safety generally (see table 1). First, a large-scale outbreak associated with consumption of *E. coli*-contaminated spinach in 2006 reduced retail expenditures of bagged spinach by 20 percent for 68 weeks (Arnade et al., 2009). An outbreak arising from *Salmonella* in serrano peppers had just concluded when FSMA was introduced to Congress in early March 2009. In addition, media reports in 2007 and 2008 that both dairy products and pet foods in China had been intentionally adulterated increased concerns about the efficacy of food safety systems in countries exporting to the United States. Finally, an outbreak caused by *Salmonella* in peanut butter in 2008 and 2009 affected more than 700 people in 46 States and may have contributed to the deaths of 9 people (Johnson, 2011).

Figure 1
Growth in consumption shares of fresh U.S. fruits and vegetables (by volume)
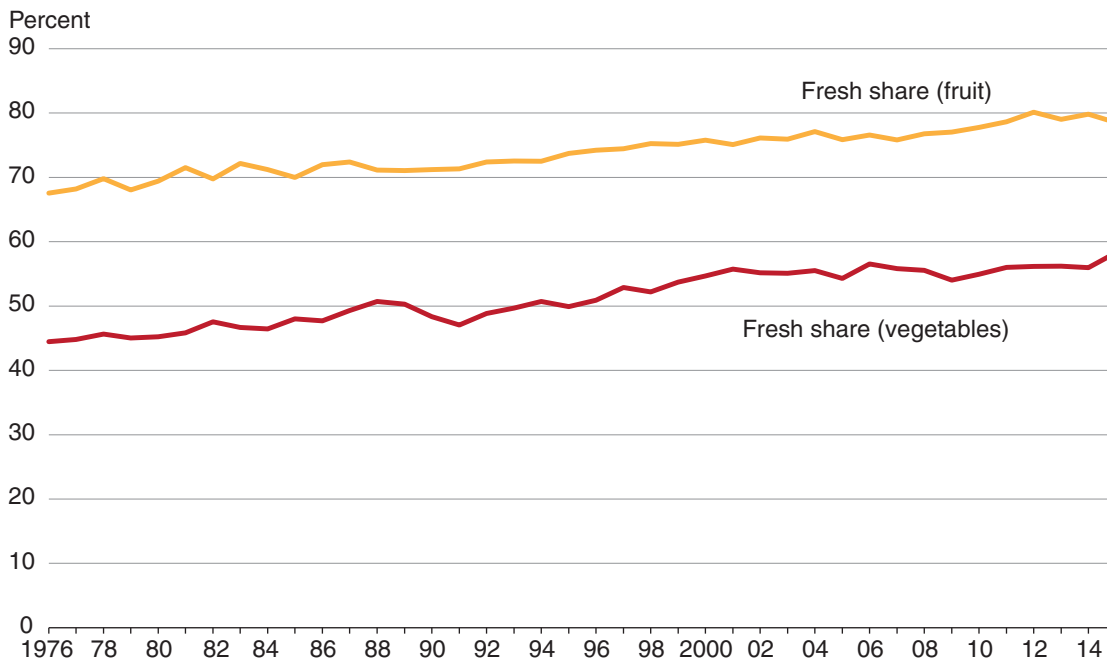
Note: Shares reflect fresh per capita use as a share of total fresh, frozen, dried, and canned per capita use. Vegetables exclude melons. Fruits exclude fruit for juicing from the share calculation.

Source: USDA, Economic Research Service (2016a, 2016b).

Table 1
Confirmed foodborne illness outbreaks arising from fruit and vegetable consumption

Year	Food vehicle	Etiology	Number of illnesses	Number of deaths
1998	Tomato	*Salmonella enterica*	86	3
1998	Unspecified fruit	Norovirus	270	0
1998	Parsley	*Shigella sonnei*	486	0
1998	Lettuce	*Campylobacter jejuni*	300	0
1999	Unpasteurized orange juice	*Salmonella enterica*	398	0
2000	Watermelon	Shiga toxin-producing *Escherichia coli*	736	1
2001	Cantaloupe	*Salmonella enterica*	50	2
2001	Tomato	*Shigella flexneri*	886	0
2002	Tomato	*Salmonella enterica*	510	0
2003	Honeydew melon	*Salmonella enterica*	68	2
2003	Almonds	*Salmonella enterica*	42	1
2003	Spinach	Shiga toxin-producing *Escherichia coli*	16	1
2003	Alfalfa sprouts	*Salmonella enterica*	26	1
2003	Corn	*Clostridium perfringens*	880	0
2003	Green onion/scallion	Hepatitis A	935	0
2004	Roma tomato	*Salmonella enterica*	429	0
2005	Basil	*Cyclospora cayetanensis*	592	0
2006	Spinach	Shiga toxin-producing *Escherichia coli*	238	5
2006	Carrot juice	*Clostridium botulinum*	4	1
2006	Peanut butter	*Salmonella enterica*	715	0
2007	Tomato	*Salmonella enterica*	10	1
2008	Serrano peppers	*Salmonella enterica*	1500	2
2008	Peanut paste	*Salmonella enterica*	714	9
2008	Watermelon	*Salmonella enterica*	594	0
2009	Melon	*Salmonella enterica*	53	1
2009	Alfalfa sprouts	*Salmonella enterica*	256	0
2010	Celery	*Listeria monocytogenes*	10	5
2011	Strawberries	Shiga toxin-producing *Escherichia coli*	15	2
2011	Cantaloupe	*Listeria monocytogenes*	147	33
2012	Cantaloupe	*Salmonella enterica*	261	3
2012	Cantaloupe	*Salmonella enterica*	33	1
2013	Mixed cut fruit	Norovirus	16	1
2013	Prepackaged leafy greens	Shiga toxin-producing *Escherichia coli*	14	1
2013	Papaya	*Salmonella enterica*	13	1
2014	Nectarine	*Listeria monocytogenes*	2	1
2014	Mung bean sprouts	*Listeria monocytogenes*	5	2
2014	Cucumber	*Salmonella enterica*	275	1
2014	Caramel apple	*Listeria monocytogenes*	35	7
2015	Prepackaged lettuce	*Listeria monocytogenes*	19	1
2015	Tossed salad	*Salmonella enterica*	252	0
2015	Cucumber	*Salmonella enterica*	907	6

Note: Data reflect outbreaks associated with fruits and vegetables with at least 250 confirmed cases or with at least 1 death and do not include outbreaks also associated with products other than fruits and vegetables or outbreaks associated with home-made foods. No such outbreaks occurred during 2016, and data were not available for 2017-18 at the time of publication.

Sources: USDA, Economic Research Service using data from U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (2018, covering outbreaks from 1998 to 2016).

Requirements of the FSMA regulations

FSMA required that FDA develop and issue certain regulations or "rules" that specify required practices and standards for farms, processors, and marketers whose products fall under FDA's jurisdiction. For general context, we provide a brief list of the main subject areas for each of the rules required by the legislation:

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (111th Congress Public Law 353, Sec. 105).
  - ° Applies to many farms that grow certain fresh-produce commodities often consumed raw.
  - ° Requires testing of agricultural water, hygiene and sanitary standards, and efforts to prevent contamination of fresh produce with animal feces, with special requirements for growers of sprouts from beans and seeds.

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Human Food (Sec. 103).
  - ° Applies to facilities that manufacture, process, pack, or hold human food (including fresh produce).
  - ° Requires development and implementation of an HARPC plan, analogous to hazard analysis and critical control points (HACCP) programs currently mandatory for processors of dairy products, juice, meats, and seafood.[4]

- Foreign Supplier Verification Program for Importers of Food for Humans and Animals (Sec. 301).
  - ° Requires importers to verify that their suppliers are compliant with FSMA.

- Accreditation of Third-Party Auditors (Sec. 307).
  - ° Sets standards for the voluntary accreditation of private companies and foreign governments to conduct audits of foreign food producers.

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Food for Animals (Sec. 103).
  - ° Requires manufacturers of food for animals to follow similar standards as required by the rule on HARPC for human food.

- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Sec. 106).
  - ° Requires most facilities (foreign and domestic) that manufacture, process, pack, or hold food to design and implement plans to protect against the intentional adulteration of food as terrorism or other acts intended to cause widespread harm to human health (FDA, 2016).
  - ° Does not apply to farms.

- Sanitary Transportation of Human and Animal Food (Sec. 111).
  - ° Requires shippers, loaders, carriers, and receivers to implement and document practices to reduce the risk that food will become contaminated during shipping (FDA, 2016).

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[4]Hazard analysis and critical control points (HACCP) is a system under which facility managers identify hazards that threaten food safety and implement a system for reducing or eliminating those hazards.

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The FSMA Produce Rule

This study focuses on the cost effects of the FSMA Produce Rule—more formally known as "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Farms covered by the Produce Rule will have specific production practices regulated along five areas: agricultural water quality, soil amendments of animal origin, worker health and hygiene, animal intrusion, and sanitary standards.[5] Improvements to these practices are expected to reduce microbial contamination at the farm level by limiting the exposure of produce to pathogens. FDA estimated the annualized cost of compliance for U.S. agriculture for each of the major rule components (FDA, 2015), along with the basic compliance activities required as part of these rule components (see table 2).[6]

Table 2
**Estimated costs of compliance with components of the FSMA Produce Rule,
from FDA Regulatory Impact Analysis, domestic farms**

Component	Compliance activities	Estimated cost ($ millions)
Agricultural water	No detectable *E. coli* in water for certain uses (including washing hands and washing food-contact surfaces) Nonzero *E. coli* standard for water applied for growing produce Several tests per year are required	16.11
Soil amendments of animal origin	Raw manure may not contact produce during application of the manure Stabilized compost must meet certain standards for bacteria	1.28
Domesticated and wild animals	Examine the growing area to identify and prevent animal fecal contamination	11.01
Worker training and health and hygiene	Workers must wash and dry hands at certain times, such as after using the toilet Workers, including those who handle food or food-contact surfaces, must receive training, including on the importance of health and hygiene	216.41
Equipment, tools, and buildings	Must sanitize equipment, tools, and buildings, especially food-contact surfaces	83.56
Sprouting operations	Taking measures to prevent introduction of dangerous microbes; treating seeds; testing irrigation water; testing for *Listeria*	5.55
Recordkeeping, administrative cost to learn the rule		31.98
Other		2.27
Total		368.17

Note: Unlike in other parts of the U.S. Food and Drug Administration's (FDA) Regulatory Impact Analysis, table 36 explicitly accounts for farms being allowed different deadlines for compliance with the rule components and the phasing-in of the agricultural water provisions. We view the timing of regulatory compliance as important and therefore elect to use this summary table. FSMA = Food Safety Modernization Act.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2015), table 36.

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[5]In addition, growers of sprouts from beans and seeds—which have a greater tendency toward microbial contamination than other produce commodities—have more rigorous requirements. Note that FDA uses 12 component areas in its Regulatory Impact Analysis, and we generalize them into five areas, plus requirements for sprouts, recordkeeping requirements, and other costs. See table 2.

[6]The FDA cost estimates converted one-time expenditures into (annualized) recurring costs based on a 10-year time horizon with a 7-percent discount rate, a method mandated by the Office of Management and Budget.

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The FSMA Produce Rule applies the same production requirements to all types of regulated farms, but the costs of compliance with FSMA will vary based on current farm practices. OSHA regulations (79 FR 33612) require field sanitation units and handwashing stations for all agricultural establishments where 11 or more employees are engaged in hand-labor operations in the field. Farm practices vary by State, too. For example, California State law—among other States' laws—also requires that farmworkers have access to toilets and hand-washing stations in the field (California Division of Industrial Relations, 2014), but this is not a requirement under Federal law for all farms; some farms will not need to incur extra costs to comply with this component of FSMA, and other farms will. As another example, wild animals are a risk to food safety in some regions but are uncommon in others.[7] So, even among fully regulated farms of the same size, costs of compliance with the rule can vary greatly depending on region, type of crop grown, and food safety practices adopted voluntarily. Our analysis does not address these inherent differences in the cost of complying with the Produce Rule, but it does draw on the differences in cost of compliance across farm size as given in the RIA.

Coverage of the Produce Rule by commodity

The Produce Rule applies only to fresh produce commodities defined by FDA to include fruits, vegetables, mushrooms, sprouts, peanuts, tree nuts, and herbs but not grains such as barley, oats, rice, wheat, and oilseeds (80 FR 74551). The following produce commodities are excluded from the rule because FDA has determined that the products are rarely consumed raw in the United States: asparagus, dry or canned beans (e.g., black, great Northern, kidney, lima, navy, and pinto), garden beets (roots and tops), sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weed), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts (FDA, 2016).

Qualified exemptions for small farms

FDA requires that farms with more than $25,000 in annual revenue from sales of covered commodities comply with the Produce Rule. Farms with sales of $25,000 or less are exempt from the rule.

The FSMA legislation specifies that the Produce Rule must provide an "exemption for direct farm marketing" (U.S. Congress, 2011, 124 Stat. 3903). As specified in the legislation, farms that qualify for this (partial) exemption must only label their products with the name and business address of the farm in a manner visible to consumers at the point of sale. The criteria for qualification are that farms must have less than $500,000 in annual revenue from sales of food (including produce) and must make more than half of their sales (in terms of value) directly to consumers, or directly to restaurants or retail food establishments within the same State or within a 275-mile radius. FDA may revoke the exemption for otherwise qualifying farms if it determines that an outbreak is associated with that farm or if conditions on the farm pose a threat to public health.

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[7]Growers generally make efforts to keep animals out of fields, not only to address food safety concerns but also to prevent animals from eating crops.

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Costs of Compliance With the FSMA Produce Rule

Under various laws and directives, regulatory agencies are required to prepare a Regulatory Impact Analysis to enumerate the costs and benefits associated with any regulation with significant costs.[8] In modeling the costs of compliance, FDA summed estimated accounting costs for farms differing by sizes within three general ranges based on total annual produce sales: very small farms ($25,001 to $250,000); small farms ($250,001 to $500,000); and large farms (more than $500,000). FDA then multiplied those estimates by the number of farms within each size category to estimate a total national cost of compliance with the Produce Rule (see table 2). The FDA analysis thus implies that all farms within a given size category have the same cost of compliance.

Compliance with FSMA entails both fixed and variable costs. Fixed costs, which do not change based on the size or output of the farm, may consist of basic bookkeeping operations to document food safety practices or water-quality tests, or labor time required to understand the regulations. Variable costs, which depend on the size of the farm, may consist of training costs for workers, supervisor compensation that depends on the number of workers on a farm, or monitoring costs that depend on the acreage or output of the farm.

If variable costs of compliance increase at a rate equal to or smaller than the rate of output as a farm expands and if fixed costs of compliance are large, then regulatory compliance requirements create economies of scale. That is, large farms have lower marginal costs of compliance with respect to output than smaller farms. Large farms have the same per-unit cost of compliance for FSMA costs that vary proportionally with farm size (e.g., certain worker hygiene requirements; animal intrusion monitoring) but a smaller per-unit cost of compliance for FSMA costs that are fixed (e.g., costs of learning the FSMA rules; accounting requirements).

Compliance with FSMA requires that farms take on both one-time costs, such as costs to management and personnel to learn the Produce Rule, and recurring costs, including water testing and sanitation of equipment. Beginning in January 2018, large farms were required to implement nearly all of the rule components. Small and very small farms can postpone implementation for 1 and 2 years, respectively. In addition, some of the rule components related to agricultural water will be implemented with a 2-year delay for each farm-size category.[9] Thus, we analyze the effects of FSMA implementation on farm costs over 2018-22 and also include in the analysis the costs of learning the Produce Rule in 2016.

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[8]Executive Orders 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995. Currently, significant costs imply that total costs for industry must exceed $144 million (in 2013 dollars) (FDA, 2014a).

[9]In September 2017, FDA (2017) issued a new proposed rule that would delay the implementation dates for agricultural water testing requirements for several years. At the time of this report, FDA had not yet issued a final rule on this topic. Our cost estimates reflect the implementation dates of the earlier, final rule published in 2015.

FDA estimated the costs of compliance with individual rule components for three sizes of fully regulated farms. Using a standardized discount rate of 7 percent,[10] FDA converted these costs into annual expenditures. The differences in compliance costs across farm size derive mainly from labor costs associated with harvesting and are discussed in detail later in this report. In constructing the estimates in the RIA, FDA did not make any substantive effort to assess how costs of compliance would differ across commodities.[11] Farm sizes and the labor used in production are closely correlated with the commodity produced. For this reason, costs of compliance with FSMA are likely to differ systematically across commodities, where commodities produced on large farms with little labor input have a relatively small added cost (as a percentage of farm revenue), while commodities produced on large farms with large labor inputs have a relatively large average cost. In addition to these economies of scale in compliance, the FSMA Produce Rule provides some explicit exemptions from the Rule's provisions.

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[10]This rate is set by the Office of Management and Budget, which oversees the procedures for cost and benefit calculations used in rule making.

[11]In two instances, FDA accounted for the collective adoption by growers of particular commodities of practices equivalent to the FSMA requirements. However, FDA's estimates of the number of farms already in compliance with components of the rule is certainly an underestimate because many farms undertake on-farm food safety practices substantially equivalent to the requirements of the components of the Produce Rule to satisfy private contractual requirements or simply to protect themselves (see, e.g., Bovay, 2017; Lichtenberg and Page, 2016), and FDA accounted for such practices in a conservative way, as we discuss in the appendix.

Contributions of This Report

As stated earlier, the FDA's Regulatory Impact Assessment does not consider how compliance costs vary across commodities or States. This study uses the FDA's estimates to compute costs of compliance by commodity as a share of revenue to facilitate more nuanced demand analysis and price forecasting (see table 3). Specifically, these data can be adapted to simulation analysis to estimate the effects of FSMA on farm and consumer prices and on producer welfare.

As discussed by Bovay and Sumner (2017), the FDA's Regulatory Impact Analysis does not consider equilibrium effects of the implementation of FSMA, instead it assumes that costs can be added to prices without affecting quantity produced, an assumption consistent with very inelastic demand. This assumption greatly simplifies the analysis since the rule's benefits (i.e., safer foods causing fewer illness) and costs (i.e., higher prices) are borne only by consumers. Bovay and Sumner (2017) simulated the equilibrium effects of FSMA implementation by calculating the specific costs of applying food safety measures to the North American fresh-tomato industry as a case study by calculating the costs of complying with the FSMA Produce Rule (as a share of revenue, based on the size distribution of farms in that industry) and then allowing the tomato market to reach a new equilibrium reflecting the shifts in supply curves for various groups of producers.

In a similar manner, we calculate the cost of compliance with the Produce Rule (as a share of revenue) for 18 fruits and 20 vegetables, nearly all the major U.S. crops affected by the rules. We calculate the average effect of FSMA implementation for covered fruits and vegetables by State, allowing for more direct insight into the distribution of compliance costs. We also summarize the expected effects of FSMA implementation crop by crop, providing insights into potential changes in the relative costs of growing various fresh-produce commodities. These cost estimates can be easily adapted to future research using a formal demand and supply framework to calculate the welfare effects for producers and consumers of regulated fresh-produce commodities.

Table 3
Side-by-side comparison of cost of compliance estimates

Breakouts by category	FDA RIA (2015b)	ERS estimates
Cost by size category	Yes	Yes
Costs by State	No	Yes
Costs by commodity	No	Yes

FDA RIA = U.S. Food and Drug Administration Regulatory Impact Analysis. ERS = USDA, Economic Research Service.

Our analysis does not independently estimate the costs of complying with individual components of the Produce Rule; rather, it draws our estimates of the costs of compliance with the Produce Rule components from the FDA's estimates contained in the RIAs (FDA, 2013, 2014a, 2015b).[12] We recognize that this approach has shortcomings. In particular, the linear interpolation method we use to estimate costs of compliance for farms across the entire distribution of farm sizes (sales values) may be inappropriate; nonlinearities may exist that are not obvious from reading the FDA RIAs. Also, reviewers have noted that FDA may overestimate or underestimate the costs of compliance with certain rule components.[13] For example, the Preliminary RIA (FDA, 2013) includes estimates of the costs of water testing and treatment for large farms that have multiple water sources; the Final RIA (FDA, 2015b) assumes that all farms have only one water source.

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[12]FDA's estimates of the costs and benefits of the FSMA Produce Rule are contained in three separate documents: the Preliminary RIA (FDA, 2013), the Supplemental Preliminary RIA (FDA, 2014a), and the Final RIA (FDA, 2015b). Each of these builds on the previous documents and incorporates comments from stakeholders; the Final RIA also incorporates revisions to the requirements of the rule.

[13]It is also worth noting that our analysis assumes that farms have not already adopted food safety practices and that all regulated farms will be required to incur the full costs of implementing the FSMA Produce Rule. As discussed, there is good evidence that many farms have adopted food safety practices, so our estimates of the effects of FSMA on farm costs are likely to be inflated.

Cost Shifts

As described earlier, to estimate the cost of implementing the FSMA Produce Rule for each commodity, we combine data on the distribution of farm sizes from USDA's 2012 Census of Agriculture with data published in FDA's RIA for the Produce Rule (FDA, 2013, 2014a, 2015b). According to the RIA, factors accounting for variations in costs by farm size include differences in the number of workers who required training and in bookkeeping costs. Most strikingly, FDA estimates that the large fixed costs of the regulations will create substantial economies of scale in their implementation.

The RIA did not disaggregate the cost of implementing the Produce Rule across commodities, providing only estimates of the average cost of implementation by farm size for three sizes of fully regulated farms and for farms that qualified for exemptions and farms not covered by the rule. FDA estimates that the full costs of implementing the Produce Rule will represent 1.56 percent of total revenue from produce sales for fully regulated farms. For large farms, however, this share is only 0.92 percent (table 4). For small and very small farms, the shares are 6.04 percent and 6.77 percent, respectively.[14] Although these estimates illustrate economies of scale in complying with FSMA, they do not provide detailed information about the distributional effects on producers of different fruit and vegetable commodities covered by the FSMA Produce Rule. By using nonpublic, farm-level data from the 2012 Census of Agriculture, we are better able to show these commodity-level effects, along with estimates of how average farm compliance costs vary at the State and county levels.

The 2012 Census of Agriculture (USDA, NASS, 2014) is the primary source of data on the production of U.S. farms and includes detailed statistics on the planted acreage of each commodity, including some distinctions as to whether goods are destined for further processing. Farm sales, however, are only reported for aggregate categories such as fruit, vegetable, and berry sales, so we are unable to identify precisely the sales value of FSMA-covered production from the Census data. We cannot generate reliable estimates of FSMA-covered sales from the acreage data because yields vary greatly. Instead, we estimate the farm-level cost of compliance with the Produce Rule as a function of farm produce sales, including the following categories: vegetables, potatoes, and melons; berries; fruits and nuts; mushrooms; and pineapples. Compliance with the Produce Rule will be phased in over several years, and we present estimates of the cost of compliance as it varies by farm size across years. Our estimates of variation in costs by crop and geographic region reflect only the recurring costs of compliance under full implementation.

We develop the cost of compliance with the Produce Rule as a linear interpolation of the point estimates from the FDA RIA. In addition, we extrapolate from FDA's estimates to generate an estimate of the cost of compliance for a minimum-sized farm, and we assume that farms with produce sales in excess of $3,450,000 would incur zero marginal cost of compliance with respect to sales. See the appendix for additional discussion on the development of cost estimates for a minimum-sized regulated farm.

Note that our estimates differ from those in the FDA RIA because we use the detailed farm-level data from the 2012 Census of Agriculture and because we break out "large" farms into several subcategories (see table 4). The large-farm category accounts for 85.6 percent of total U.S. produce sales.

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[14]See appendix for details on how we calculate these percentages from the FDA's estimates.

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USDA, Economic Research Service

Table 4
Average cost of full compliance with the Produce Rule, by farm sales category

Category (value of annual produce sales)	Average cost of compliance (dollars)	Average cost of compliance as a share of revenue (percent)
Very small, qualified ($25,000 to $250,000)	1,738	2.45
Small, qualified ($250,000 to $500,000)	1,738	0.51
Very small, fully regulated under FSMA Produce Rule ($25,000 to $250,000)	5,560	6.77
Small, fully regulated ($250,000 to $500,000)	21,136	6.04
Large, fully regulated ($500,000 and above)	29,228	0.92
$500,000 to $700,000	24,360	4.17
$700,000 to $1,000,000	25,451	3.07
$1,000,000 to $1,600,000	27,315	2.19
$1,600,000 to $3,450,000	32,111	1.38
$3,450,000 and above	37,115	0.33

Notes: Estimates reflect the full cost of compliance upon implementation of all rule components in 2020 to 2022 (depending on farm size), relative to a farm that has not adopted any food safety practices. FSMA = Food Safety Modernization Act.

Sources: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture.

We then use our estimates of the cost of compliance by farm size to generate our estimates of the cost of compliance for affected farms by State and county. Importantly, these estimates are only based on farms growing fruits and vegetables. In many counties where the geography or climate makes large-scale fruit or vegetable production infeasible, some small farms may still operate to serve local markets. For example, Idaho's mountains and cold temperatures likely prevent large-scale fruit and vegetable farms. In these regions, estimated costs are likely to be higher with relatively few farms being be affected. Also, our estimates do not cover fruits and vegetables either grown for canning or infrequently consumed raw, such as asparagus, sweet corn, potatoes, and sweet potatoes. Consequently, our estimates of the Produce Rule compliance costs are not relevant to the cost of producing those goods.

In a similar manner, we use our estimates of the cost of compliance by farm size to generate estimates of the cost shares by commodity. First, using NASS data, we calculate each farm's share of the total planted acres for each of the considered commodities. Next, we multiply each farm's share of national acreage for each commodity by that farm's cost of implementing FSMA as a percentage of sales. For example, if the share of strawberry acres is 65 percent on large farms, 25 percent on small farms, and 10 percent on very small farms, then the cost of compliance (as a share of revenue) we report for the strawberry commodity will be the average of the large, small, and very small costs for the generic farm multiplied by those shares. Since compliance costs are higher for small farms, this method estimates higher costs for crops that are produced by smaller farms. This method also incorporates the effects of farms producing more than one type of produce. If a farm maintains only a small acreage of cucumbers, for example, then that farm's contribution to our estimate of the average implementation costs for cucumbers will be similarly small.[15]

[15]Importantly, this method only addresses farm size as source of variation in the cost of implementing FSMA and should be interpreted with the understanding that data are not available to determine a more specific cost estimate that account for differences in yields or labor use.

Results

Again, our estimates of the recurring costs of implementing the Produce Rule are likely, in many cases, to be overestimates because we have not excluded all noncovered production (specifically, fruit and vegetables grown for canning and vegetables designated as "rarely consumed raw").[16] These estimates depend on the value of produce sales and not on other factors, such as number of workers per farm or current level of adoption of food safety practices.

For vegetables, the estimated annual cost of compliance as a share of revenue ranges from 0.3 percent (romaine lettuce) to 3.0 percent (snap beans). For fruits, the estimated cost share ranges from 0.7 percent (honeydew) to 3.6 percent (mangoes). However, we note that imports account for a large share of U.S. consumption of mangoes, avocadoes, and bananas—the three fruits with the highest estimated cost of compliance. If imports of these commodities are grown on larger farms than in the United States, they will have a lower expected cost of compliance. Among fruits primarily grown domestically, the highest estimated cost of compliance is 3.0 percent (pears).

Table 5
Estimated recurring cost of compliance with the Produce Rule by regulated commodity upon full implementation of the Rule in 2022 and import shares

Vegetables	Cost as share of revenue (percent)	Import share (percent)	Fruits	Cost as share of revenue (percent)	Import share (percent)
Artichokes	0.36	80.5	Apples	2.18	7.5
Broccoli	0.44	19.5	Apricots	2.02	3.5
Cabbage	1.59	8.2	Avocadoes	3.53	81.4
Carrots	0.97	15.1	Bananas	3.47	99.9
Cauliflower	0.43	14.1	Cantaloupes	1.42	43.6
Celery	0.42	6.1	Cherries, sweet	2.70	7.9
Cucumbers	2.12	73.5	Grapefruit	1.72	2.9
Lettuce (head)	0.33	6.9	Grapes	2.06	46.1
Lettuce (leaf)	0.39	5.4	Honeydew	0.70	42.0
Lettuce (romaine)	0.31	5.4	Mangoes	3.57	99.9
Onions (dry bulb)	1.72	18.3	Nectarines	1.23	8.7
Peppers (bell)	1.29	59.3	Oranges (navel)	2.16	12.5
Peppers (chile)	2.63	NA	Peaches	2.30	8.7
Snap beans	2.99	31.4	Pears	2.97	19.8
Spinach	0.84	4.8	Plums	2.30	26.9
Squash	2.50	NA	Strawberries	1.31	12.6
Tomatoes	1.07	52.5	Tangerines	1.34	28.0
			Watermelons	2.65	32.9

Note: NA = Not available. Our cost of compliance estimates only apply to farms producing raw agricultural commodities subject to the Food Safety Modernization Act (FSMA) regulations. Fruits and vegetables processed with a "kill step" that eliminates the risk of pathogens (such as canned foods) are not subject to FSMA regulations.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture (cost as share of revenue); and USDA, Economic Research Service (2016a, 2016b).

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[16]Canned foods and processed foods that undergo a kill step are not subject to the Produce Rule. Unfortunately, shares of processed and canned production are only broken out at the national, but not at the State, level in NASS data. In essence, our analysis deals with crops grown for processing by assuming that, for example, pickling cucumbers and cucumbers to be sold fresh are grown on the same sizes of farms.

Note that while the FSMA Produce Rule does not explicitly create differential costs for producers based on location within the United States, the differential effects of FSMA implementation by farm size have implications for the long-run competitiveness of farming in States where produce tends to be grown by smaller enterprises.[17] This analysis aggregates our estimates of farm-level costs of compliance to the State level. It is important to note that these estimates only apply to farms regulated by the FSMA Produce Rule and not subject to an exemption.

Many States where produce is grown by relatively small farms will have high costs of compliance with the Produce Rule as a share of sales, including Alabama (3.7 percent of produce sales), Iowa (3.4 percent), and Kentucky (3.3 percent) (table 6, fig. 2). Conversely, States where fresh-produce production is dominated by large farms, such as Arizona (0.6 percent), Florida (1.3 percent), California (1.3 percent), and Washington (1.4 percent), have relatively low costs of compliance as a share of sales. Recall that these results are driven by total value of production in the State and by the number and size distribution of farms. There are a few exceptions: Nebraska (1.2 percent) and North Dakota (1.3 percent) are estimated to have lower costs of compliance than Florida. This difference in costs is driven by the exemptions for which many produce-growing farms in Nebraska and North Dakota will be able to qualify. County-level differences in estimated costs reflect local geography affecting crop choice and, relatedly, farm size, but also have an idiosyncratic component. For instance, in the Great Plains (e.g., Minnesota, South Dakota, and Nebraska) and west Texas, high-cost counties are often adjacent to low-cost counties or counties with no data. This patchy pattern likely reflects the relative infrequency of large-scale fruit and vegetable farms in these areas compared to counties in California, Florida, and Arizona, where farms are more uniformly large and numerous.

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[17]For small farms to obtain qualified exemptions, they must make the majority of their sales directly to consumers, or to other end users within the same State or within a 275-mile radius. This criterion allows farms in large States (geographically) and population-dense regions of the country to sell their products to more buyers and creates an implicit advantage for farms in those regions. For the sake of our analysis, we assign small farms with direct sales exceeding half of revenue as qualified for an exemption.

Table 6

Estimated cost of compliance, as a share of revenue, by State, upon full implementation in 2022

State	Estimated cost of compliance as share of revenue (percent)	State	Estimated cost of compliance as share of revenue (percent)
Arizona	0.61	Michigan	2.59
Nevada	1.14	Oklahoma	2.61
Nebraska	1.16	Hawaii	2.62
North Dakota	1.28	Wyoming	2.66
Florida	1.31	Oregon	2.67
California	1.32	Kansas	2.71
Washington	1.38	New Hampshire	2.72
Tennessee	1.45	Delaware	2.81
Pennsylvania	1.53	Connecticut	2.84
Idaho	1.67	Louisiana	2.87
Colorado	1.91	Maryland	2.87
South Carolina	1.92	Montana	2.88
Wisconsin	1.97	New York	2.88
Georgia	1.97	Massachusetts	2.97
Maine	2.00	Indiana	2.97
New Mexico	2.05	Rhode Island	2.99
North Carolina	2.29	Vermont	3.00
West Virginia	2.36	Arkansas	3.08
New Jersey	2.40	Minnesota	3.21
Virginia	2.42	Kentucky	3.28
Ohio	2.43	Mississippi	3.31
Utah	2.46	Iowa	3.35
Texas	2.47	Alabama	3.67
Missouri	2.48	South Dakota	3.73
Illinois	2.53	Alaska	3.82

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture (2015b).

Figure 2
County-level differences in FSMA implementation costs
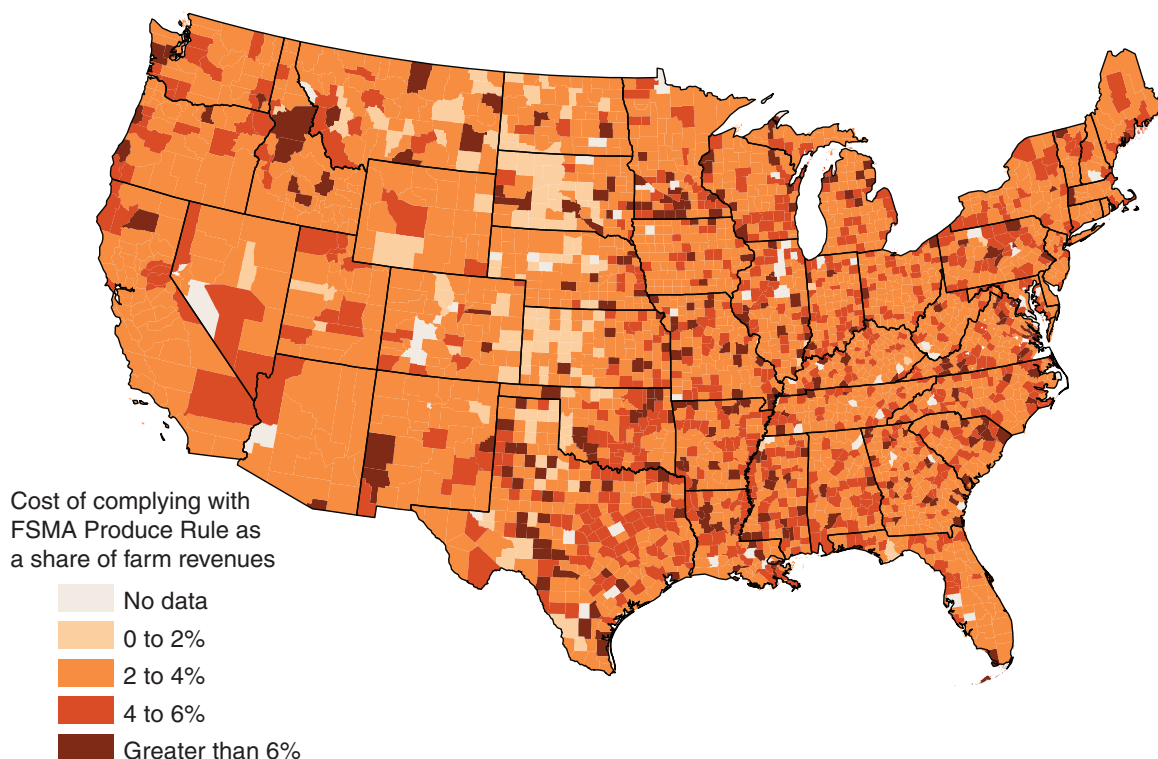
Cost of complying with
FSMA Produce Rule as
a share of farm revenues

- No data
- 0 to 2%
- 2 to 4%
- 4 to 6%
- Greater than 6%

Note: FSMA = Food Safety Modernization Act.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture.

Lastly, implementation of the Produce Rule is delayed by 1 and 2 years for small and very small farms, respectively, meaning that they will not be required to comply until January 26, 2019, and January 26, 2020, respectively. Compliance with the agricultural water provisions is delayed 2 additional years for all farms.[18] Given these timelines, we find that fully regulated very small farms will incur costs between 6.5 and 6.8 percent of total produce sales between 2020 and 2022, small farms will incur costs between 5.9 and 6.0 percent of produce sales between 2019 and 2022, and large farms will incur costs of 0.9 percent of produce sales between 2018 and 2022. After the initial costs of learning the rule in 2016 and 2017, exempt farms that are very small farms will incur costs of 2.5 percent of produce sales between 2020 and 2021 and exempt farms that are small farms will incur costs of 0.5 percent of sales between 2019 and 2021.

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[18]In September 2017, FDA (2017) proposed a further delay in the implementation of the water testing component of the rule. This change has not been finalized and is not incorporated in our estimates.

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Table 7
Average dollar and percentage costs of implementing FSMA Produce Rule regulations, by farm size and year

	Average cost of compliance										
	Costs for exempt farms ($)			Costs for regulated farms ($)							
Year	Fully exempt	Very small qualified	Small qualified	Very small	Small	Large (all)	Large (a)	Large (b)	Large (c)	Large (d)	Large (e)
2016	171	288	288	2,885	6,725	5,550	5,550	5,550	5,550	5,550	5,550
2017	0	0	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	0	28,573	23,926	24,968	26,747	31,325	36,102
2019	0	0	1,738	0	20,769	28,573	23,926	24,968	26,747	31,325	36,102
2020	0	1,738	1,738	5,375	20,769	29,228	24,360	25,451	27,315	32,111	37,115
2021	0	1,738	1,738	5,375	21,136	29,228	24,360	25,451	27,315	32,111	37,115
2022	0	1,738	1,738	5,560	21,136	29,228	24,360	25,451	27,315	32,111	37,115
	Average costs as share of sales (percent)										
2016	2.38	0.41	0.08	3.51	1.92	0.17	0.95	0.67	0.44	0.24	0.05
2017	0	0	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	0	0.90	4.10	3.01	2.14	1.35	0.32
2019	0	0	0.51	0	5.93	0.90	4.10	3.01	2.14	1.35	0.32
2020	0	2.45	0.51	6.55	5.93	0.92	4.17	3.07	2.19	1.38	0.33
2021	0	2.45	0.51	6.55	6.04	0.92	4.17	3.07	2.19	1.38	0.33
2022	0	2.45	0.51	6.77	6.04	0.92	4.17	3.07	2.19	1.38	0.33

Note: FSMA = Food Safety Modernization Act. Each year begins on January 26. Farm sizes are based on annual produce sales: Very small = $25,000 - $250,000; Small = $250,000 – $500,000; Large = (a) $500,000 - $700,000; (b) $700,000 - 1,000,000; (c) $1,000,000 - $1,600,000; and (d) $1,600,000 - $3,450,000; and (e) $3,450,000 and above.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture.

Given the timing of implementation, we note that the geographical areas and commodities estimated to have higher costs of compliance, upon full implementation in 2022, will have somewhat lower costs in the intervening years. As discussed earlier, nearly 86 percent of the value of total U.S. produce sales is generated by farms with at least $500,000 in annual sales, so most of the cost increase for most commodities will be seen in 2018.

Conclusions

As the Food Safety Modernization Act and other laws are enacted, a key concern is how regulatory costs vary across producers and crops and which types of businesses gain relative advantages from regulatory implementation. In this study, we construct farm-level estimates of the cost of complying with FSMA's Produce Rule and report aggregate estimates of the cost of compliance for farms grouped by size (annual produce sales) and average costs of implementation by commodity and by State and county. Our analysis finds that differences in implementation costs can vary substantially across crops, with average compliance costs ranging from 0.3 percent of farm revenue for romaine lettuce to 3.0 percent of farm revenue for snap beans. States growing fruit and vegetables on larger farms—such as Arizona, Florida, California, and Washington—are likely to face lower implementation costs than States growing produce on smaller farms—such as Alabama, Iowa, and Kentucky.

A few caveats should be mentioned. First, our estimates of the cost of compliance with FSMA depend entirely on farm-level produce revenue, building on estimates from the FDA's Regulatory Impact Analysis. They do not account for labor or equipment costs, which vary by crop and by State. Second, we do not have Census data on farms' sales of the specific produce commodities covered by the Produce Rule, or sales of crops designated for canning (which would be exempt from coverage under the Produce Rule). Although we do have information on acreage by commodity and also acreage of vegetables to be sold for processing, the relationship between acreage and sales is nonlinear and varies across geography, time, and individual farm, so we can only use total produce sales and not focus on crops and farms that will be covered by the Produce Rule. Third, we do not account for the voluntary implementation of any food safety practices, which may have already been required by buyers or as part of marketing orders or agreements and may not necessarily align with FSMA requirements. The second and third caveats imply that we have overestimated the cost of implementing the rule. In fact, we regard the estimates presented in this report as upper bounds on the cost of implementing the FSMA Produce Rule, given FDA's estimates of the costs of compliance with individual rule components. Fourth, these estimates cover only domestic U.S. farms and not foreign farms that export to the United States. As discussed by Bovay and Sumner (2017), the Foreign Supplier Verification Program, which imposes additional costs on importers, is likely to make imports costlier and reduce the share of imports in U.S. consumption. Bovay and Sumner (2017) find that the share of imports of fresh tomatoes, for example, is likely to decrease under the program by up to 6 percentage points.[19] Finally, the estimates of commodity-level increases in farm costs must not be confused with estimates of the increases in retail prices that can be expected to result from implementation of the Produce Rule, which one might calculate using a fully specified model of supply and demand. A study of this type would incorporate additional information about demand shifts and pass-through of costs from farm to retail prices to simulate the total economic effects of implementing the Produce Rule.

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[19]If, however, compliance with the FSMA Produce Rule is cheaper in foreign countries because of lower labor costs or other reasons, the import share in U.S. consumption may increase.

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# Appendix—Developing the Estimates of Farm-Level Costs of Compliance

Similar to Bovay and Sumner (2017), we use estimates from the U.S. Food and Drug Administration's (FDA) Regulatory Impact Analyses (RIA) for the Food Safety Modernization Act (FSMA) Produce Rule (FDA, 2013, 2014a, 2015b) as the basis for our simulated shifts in producer costs. The RIA for the Produce Rule provides estimates of the costs of compliance for very small, small, and large farms, in addition to estimates for farms that qualify for partial exemptions and estimates of the costs of learning the rule for farms that are not covered by the rule. These costs are reported on a line-by-line basis, and for many of the rule components, costs are reported per employee or per acre. This detailed information enabled us to construct an estimate of the cost of compliance for the smallest possible fully regulated farms—those with $25,001 in produce sales, on 1 acre, with one employee, and so on. Based on this minimum cost of compliance and the three point estimates from FDA, we generated estimates of the cost of compliance with the Produce Rule for a farm with any given value of sales. We assumed that, for all farms with at least $3.45 million in sales in a given year, the marginal cost of compliance with FSMA, with respect to sales, is zero.[20] As mandatory compliance with various parts of the Produce Rule and the Foreign Supplier Verification Program (FSVP) Rule is staggered over the 5 years beginning in 2018, we were able to construct estimates of the cost of compliance across 2018-22 (see appendix figure A-1). The rules will be fully implemented by 2022, so the cost of compliance in 2022 is applied in all subsequent years. (As FDA does in the RIA, we assume that farms incurred costs to learn the rule in 2016.)

In order to estimate the commodity-level farm cost effects of implementing the FSMA Produce Rule, the next step was to calculate the share of each farm's acreage dedicated to each regulated commodity from the restricted-access Census of Agriculture data from USDA's National Agricultural Statistics Service. We used this information to calculate acreage-weighted average cost of implementation, by commodity. In other words, for a given commodity, we calculated the weighted average of costs of implementation by summing, across farms, the product of farm costs of implementation and acreage share for that commodity.

For example, suppose that there are three farms producing carrots. Both of the first two farms have compliance costs equal to 6.5 percent of revenue and produce on 20 percent of all carrot acreage (details for how these numbers might be calculated are described in the next section). The third farm has compliance costs equal to 3.5 percent of revenue and produces on the remaining 80 percent of carrot acreage. Then, the cost of compliance for carrots as a whole is 4.1 percent (=6.5 percent x .2 + 3.5 percent x .8).

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[20]As discussed by Bovay and Sumner (2017), $3.45 million is the average annual sales for a large farm—all those with more than $500,000 in sales—according to the RIA. We have no basis for extrapolating the cost of compliance with FSMA for farms larger than this, but it is reasonable to assume that the costs are fixed beyond a certain size level.

Appendix figure A-1
Cost of compliance with FDA Produce Rule as a function of farm sales

Cost of compliance ($)
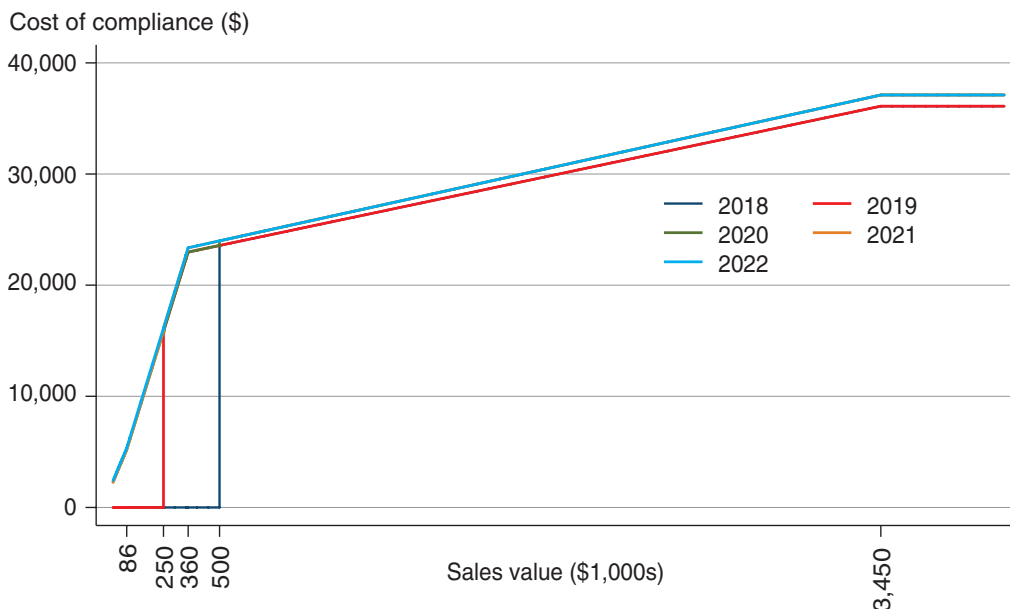
Note: FDA = U.S. Food and Drug Administration. Farms with less than $25,000 in annual produce sales are not covered by the Food Safety Modernization Act's Produce Rule. FDA presents estimates for very small farms (with sales of more than $25,000 and no more than $250,000 and average sales of $86,000); small farms (with sales of more than $250,000 and no more than $500,000 and average sales of $360,000) and large farms (with sales of more than $500,000 and average sales of $3,450,000).

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b).

As mentioned in the conclusion section of this report, this method has drawbacks. For example, consider two farms, A and B, selling produce for fresh use and fully regulated under the FSMA Produce Rule. If A grows 20 acres of tomatoes and 20 acres of apples and B grows 20 acres of tomatoes and 20 acres of strawberries, then our method overestimates the cost of compliance with the FSMA Produce Rule for tomatoes grown by farm B simply because the farm's total revenue is higher (given that per-acre revenue is higher for strawberries than apples).[21] If we had farm-level sales data by produce commodity for FSMA-regulated commodities, we would eliminate this short-coming in our analysis. However, such data are unavailable from the Census of Agriculture, and other data sources suggest that the prices and yields of fresh-produce commodities are too highly variable to be used as an input in our model. A second shortcoming is more basic: the FDA's RIA involves the assumption that farm costs of compliance with the FSMA Produce Rule are a function of farm sales of regulated commodities. This suggests that higher priced products, such as Honeycrisp apples, would be associated with higher costs of compliance with FSMA than lower priced products, such as Red Delicious apples. (This is one of several shortcomings of the FDA's Regulatory Impact Analysis, on which all of our analysis is based.) Although these shortcomings of our approach cannot be overcome, our analysis provides the first evidence on commodity-specific effects and paints an illustrative picture of the distributional effects of FSMA implementation across commodities and geographic regions.

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[21]Note, however, that our method does not ascribe the same revenues to 20 acres of tomatoes as 20 acres of strawberries.

In the Preliminary RIA (FDA, 2013), to which the Final RIA (FDA, 2015b) serves as an amendment, FDA estimated the costs of complying with approximately 100 individual rule components and aggregated these to present average and total costs across all regulated farms, within several categories. We refer to the cost estimates for the individual rule components as "line-item cost estimates." We use the line-item cost estimates as the basis for our analysis because, in its aggregation, FDA excluded a small number of farms (1,117 out of 40,211, or less than 3 percent) from incurring additional costs to comply with certain rule components on the basis of those farms undergoing USDA Agricultural Marketing Service audits for compliance with Good Agricultural Practices (GAPs), being fresh-tomato growers in Florida (where fresh tomatoes have been required to be grown under GAPs since 2008), or having status as members of the California or Arizona Leafy Greens Marketing Agreement, or the California Tomato Farmers Cooperative. Thus, the aggregate total costs of compliance presented in the FDA analysis cannot be interpreted as the sum of costs for all fully regulated growers who have zero baseline compliance; instead, the FDA's aggregation reflects partial compliance with the FSMA Produce Rule by about 3 percent of growers. Given that other evidence suggests the share of growers adopting GAPs is substantially higher than 3 percent,[22] we were left with two options: to reassess FDA's estimate of the share of growers in compliance with GAPs, in the baseline, along with the detailed information about whether their GAPs compliance brought them into compliance with each individual rule component; or to calculate costs under the simplifying assumption that zero growers were in compliance in the baseline and represent our estimates as upper bounds on compliance costs. In the absence of better information on GAPs adoption, we chose the latter option. We also calculate our costs based on their phased-in compliance, discounting the costs for rules that will not be required for all farms until 2022. For these two reasons, our table 3 estimates differ slightly with those presented in the FDA's main summary estimates.

Details of the cost functions

To construct our estimate of the cost of compliance with an individual rule component for a minimum-size regulated farm, we used one of three methods, depending on how line-item cost estimates were presented in the RIA. In the case of line-item costs presented as a function of the number of workers at very small, small, and large farms, we calculated the costs for a farm with one operator and no employees. Where line-item costs were presented as a function of farm acreage, we calculated costs for a one-acre farm. Finally, where costs were not presented as a function of farm size, we used the line-item costs for a very small farm. Combining these three approaches, these calculations yielded estimates of the cost of compliance for a minimum-size farm of $2,885 to learn the rule in 2016 or 2017; $2,278 in 2020 and 2021 before the water rule is required to be fully implemented; and $2,430 upon full implementation in 2022.

Implementation of the Produce Rule was required beginning January 26, 2018. (Sprout growers were required to begin complying earlier, but we ignore this industry throughout.) Consistent with the FDA RIA, we assume that farms incurred costs to learn the rule in 2016. As given in the RIA, these costs will be $5,550 for large farms; $6,725 for small farms; and $2,885 for very small farms.

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[22]See Bovay (2017) and Bovay and Sumner (2017) for reviews of the evidence on grower adoption of food safety practices.

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In 2018, large farms (those with more than $500,000 in annual sales of food) are required to implement the rule. Based on the estimates given in the RIA, we assume that the costs of compliance for these farms in 2018 and 2019 will be $23,569 plus $4.25 for every additional $1,000 in sales (beyond $500,000), with a maximum of $36,102.

Beginning on January 26, 2019, small farms (those with more than $250,000 and no more than $500,000 in annual sales of food) will be required to implement the Produce Rule. In 2019 and 2020, the cost for these farms will be $15,836 plus $64.89 for every $1,000 in sales above $250,000 and below $360,000. For sales above $360,000, the marginal cost of compliance will be $4.25 for every $1,000 in sales.

Beginning on January 26, 2020, very small farms (those with more than $25,000 and no more than $250,000 in annual sales of food) will be required to implement the rule, and large farms will begin being required to implement all components of the agricultural water rule. For very small farms, the cost of compliance in 2020 and 2021 will be $2,278 plus $47.80 for every $1,000 in additional sales beyond $25,000, up to $86,000 in sales; and for every $1,000 in sales over $86,000, the marginal cost will be $64.89. For large farms, the cost in 2020 and subsequent years will be $23,986 plus $4.45 for every $1,000 in sales over $500,000, up to a maximum of $37,115.

In 2021, small farms will be required to implement all components of the agricultural water rule. In 2021 and subsequent years, the cost of compliance for small farms will be $16,141 plus $65.65 for every $1,000 in sales above $250,000, up to $360,000 in sales. For sales above $360,000, the marginal cost will be $4.45 for every $1,000 beyond $360,000.

In 2022, very small farms will be required to implement all components of the agricultural water rule. In 2022 and subsequent years, the cost of compliance for very small farms will be $2,430 plus $48.26 for every $1,000 in sales above $25,000, up to $86,000 in sales. For sales above $86,000, the marginal cost will be $65.65 for every $1,000.

Finally, we also calculated the cost of compliance as a share of sales for farms that qualify for a partial exemption and for those that will not be covered by the rule. The FDA's estimated cost of compliance for these farms is a constant for qualified farms, $288 to learn the rule and $1,738 in recurring costs. For farms that sell less than $25,000 in produce, FDA estimates a one-time cost of learning the rule at $171, and no additional costs in subsequent years.

Appendix figure A-1 shows the cost of compliance estimates used in this analysis, as a function of farm sales, for 2018-22. Appendix table A-1 shows the distribution of farms used in the cost of compliance calculations by size by States.[23] While States with larger compliance costs typically have large shares of small and very small farms, the relationship is not exact because farms' size can vary substantially within these size categories.

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[23]Because we estimate costs for farms that produce multiple regulated crops, we are unable to make a table similar to appendix table A-1 with commodity-level cost estimates by size of farm.

Appendix table A-1
Numbers of farms used in cost-of-compliance calculations, by size and State

State	Number of farms	Farm size		
		Very small	Small	Large
Alabama	355	313	20	22
Alaska	28	23	<10	<10
Arkansas	177	146	13	18
Arizona	262	156	14	92
California	17,494	10,590	2,104	4,800
Colorado	365	197	46	122
Connecticut	240	199	20	21
Delaware	130	84	11	35
Florida	2,777	1,835	291	651
Georgia	1,013	671	97	245
Hawaii	521	432	38	51
Idaho	669	247	103	319
Illinois	509	422	47	40
Indiana	337	245	41	51
Iowa	153	142	<10	<10
Kansas	95	83	<10	<10
Kentucky	272	264	<10	<10
Louisiana	207	174	14	19
Maine	519	355	45	119
Maryland	347	258	43	46
Massachusetts	638	508	57	73
Michigan	1,544	1,115	172	257
Minnesota	1,266	969	149	148
Mississippi	293	252	21	20
Missouri	320	259	25	36
Montana	199	69	110	20
Nebraska	122	65	32	25
Nevada	25	16	<10	<10
New Hampshire	119	101	<10	<10
New Jersey	612	381	<10	164
New Mexico	319	221	32	66
New York	1,560	1,136	161	263
North Carolina	777	594	11	172
North Dakota	182	25	67	90
Ohio	530	431	52	47
Oklahoma	381	353	19	<10
Oregon	1,907	1,301	224	382
Pennsylvania	1,329	1,060	101	168
Rhode Island	52	41	<10	<10
South Carolina	363	300	24	39
South Dakota	25	24	<10	<10
Tennessee	189	135	25	29
Texas	1,487	1,202	101	184

Appendix table A-1
Numbers of farms used in cost-of-compliance calculations, by size and State—continued

State	Farm size			
	Number of farms	Very small	Small	Large
Utah	137	103	15	19
Virginia	438	351	41	46
Vermont	151	125	15	11
Washington	2,720	1,448	378	894
West Virginia	98	79	<10	15
Wisconsin	1,305	933	125	247
Wyoming	7	<10	<10	<10
All States	45,476	30,437	4,925	10,114

"<10" = Value is less than 10 and withheld from reporting.

Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, Census of Agriculture (2012).

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