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# Implementation challenges of the food safety modernization act: Evidence from a national survey of produce growers



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#### ABSTRACT

The Produce Rule implementing the Food Safety Modernization Act establishes on-farm standards for agricultural water, animal-based soil amendments, domesticated and wild animal intrusion, employee health and hygiene, and building and equipment sanitation. Many produce growers fear that the Rule will require extensive operational changes that may hamper their competitiveness. We use data from an original national survey of fruit and vegetable growers to estimate current usage of food safety practices—and thus the likely extent of change—required by the Produce Rule among growers falling into the size classes specified by the Rule, among growers self-identifying as sustainable, and among growers of different types of crops (vegetables, berries, fruits and tree nuts). We find that the Rule will require changes in all food safety practices for at least some produce growers. The greatest degree of change affects a handful of food safety practices: water sampling and testing, field inspections, building sanitation, equipment and tool sanitization, and recordkeeping. Additionally, small and sustainable growers lag behind larger and conventional growers in adoption of many of the food safety practices required by the Produce Rule, such as sampling and testing, field inspections, employee sanitation and hygiene, and recordkeeping.

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#### 1. Introduction

The Food Safety Modernization Act [FSMA], signed into law in January 2011, marked a major shift in the Food and Drug Administration's [FDA] approach to food safety from outbreak response to prevention-based controls. The Act gave the agency authority to require the use of sanitation measures in growing, harvesting, packing, and holding of fresh fruits and vegetables in order to reduce the incidence of foodborne illness, a large share of which have been attributed to fruits and vegetables (Painter et al., 2013). The FDA has enacted a series of rules to implement FSMA, one of which is designed to reduce food safety risks associated with consumption of fresh produce. Officially known as Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, the Produce Rule was finalized in November of 2015 and became effective in January of 2016. It establishes agricultural production standards for: (1) agricultural water; (2) biological soil amendments of animal origin; (3) health and hygiene; (4) intrusion of domesticated and wild animals; and (5) sanitation of equipment, tools, and buildings (for details of the Rule see Food and Drug Administration, 2015).

The Produce Rule affects farm operations with annual produce sales of \$25,000 or more that grow and sell produce that is typically consumed raw and not intended for commercial processing (e.g., canning, etc.). Additionally, farms with annual produce sales less than \$500,000 that sell a majority of food directly to a nearby qualified end-user (i.e. a consumer, restaurant, or retail food establishment located in-state or within 275 miles of the farm) qualify for direct marketing modified requirements and need not meet the food safety standards in the Rule. Smaller farms have more time to adopt the food safety provisions established in the Rule. Farms with annual sales of \$25,000 to \$250,000 (designated "very small" farms) have four years to comply with most provisions; farms with annual sales of \$250,000 to \$500,000 (designated "small" farms) have three; and farms with annual sales over \$500,000 ("medium/large" farms) have two. All farms have two

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<sup>&</sup>lt;sup>1</sup> The Produce Rule does not designate a label for these farms, so we refer to them as "medium/large" farms throughout the text.

additional years to meet water quality standards.<sup>2</sup>

Many growers fear that the Rule will require extensive operational changes that may hamper their competitiveness (Ribera and Knutson 2011; Ribera et al., 2016). Those fears are especially pronounced among small growers, who worry about compliance costs driving them out of business. Sustainable growers, too, worry that the Rule may prohibit production practices like the use of biological soil amendments and grazing livestock essential to many of their integrated farming systems.

There is limited publicly available information on the extent to which these implementation problems are likely to arise. This paper addresses that gap using data from an original national survey of fruit and vegetable growers. We use this data to estimate current usage of food safety measures—and thus the likely extent of change—required by the Produce Rule. We examine the extent to which current practices fall short of FSMA requirements for growers falling into the size classes specified by the Rule, for growers self-identifying as sustainable, for growers of different types of crops (vegetables, berries, fruits and tree nuts), and for growers in different regions.

Information on current usage of on-farm produce safety measures is quite limited. A relatively small number of studies have been conducted, none of which is as comprehensive as ours in terms of geographic scope or practices covered. Rangarajan, Pritts, Reiners, and Pedersen (2002) use data from a survey of 213 New York fruit and vegetable growers to study the prevalence of food safety practices related to testing and sanitation of agricultural water, manure management, composting processes, and recordkeeping. They find that small farms in particular required additional training related to recordkeeping, composting processes, and sanitation of wash water. Cohen, Hollingsworth, Olson, Laus, and Coli (2005) use data from a survey of 297 New England fruit and vegetable growers to analyze the prevalence of food safety practices related to water quality, soil amendments, employee health and hygiene, field sanitation, and recordkeeping, and find that the majority of farmers employed good agricultural practices across all practices, Hultberg, Schermann, and Tong (2012) use data from a survey of 246 Minnesota vegetable growers, 77% of whom farm 15 acres or less, and find that the majority of respondents believe they comply with many food safety best practices (e.g., worker hygiene practices, washing of harvest containers, tool sanitation, and water treatment, etc.), but are lagging in a number of key food safety areas. Becot, Nickerson, Conner, and Kolodinsky (2012) use data from 17 survey responses and 10 in-depth interviews with small and medium size Vermont fruit and vegetable growers to assess usage and estimate the costs of Good Agricultural Practice [GAP] requirements. They find that non-GAP-certified growers are less likely to wash or cool produce but no differences between GAPcertified and non-GAP-certified growers in terms of worker sanitation. Marine, Martin, Adalja, Mathew, and Everts (2016) study the effects of farm size, tenure, and marketing channel on vegetable growers' use of GAPs using data from 2010 and 2013 surveys of 313 mid-Atlantic vegetable growers that participated in GAP training. They find that implementation of GAPs varied significantly with marketing channel, but not with farm size or tenure. In particular, growers that sold produce primarily through wholesale channels were more likely to maintain written policies, test irrigation water, and complete GAP certification. Lichtenberg and Page (2016) use data from a survey of 47 leafy green and tomato growers in the MidAtlantic region to assess prevalence and cost of food safety practices required under the Produce Rule of FSMA. They find that majorities of growers in their sample employ most practices required by the Rule, but that some growers will need to implement changes in food safety practices. Farm size affected only the use of sampling and testing (including water, soil amendments, and product).

Concerns over whether the Produce Rule will put smaller growers at a competitive disadvantage have motivated several studies of the effect of farm size on the costs of implementing practices like those required under the Produce Rule. The evidence on that score suggests that smaller operations usually have higher costs per acre and are thus more likely to face greater challenges in implementing Produce Rule requirements (see for example Parker et al., 2012). Using data from a survey of 49 California grower, Hardesty and Kusunose (2009) find significant economies of scale in implementing practices required under the Leafy Greens Marketing Agreement, whose requirements are similar to those of the Produce Rule (see for example Parker et al., 2012). Adalja and Lichtenberg (2018), using data from a national survey of produce growers, also find evidence of substantial economies of scale in implementing practices required under the Produce Rule, as do Lichtenberg and Page (2016) using data from a survey of Mid-Atlantic tomato and leafy greens growers. Studies based on crop budgets from California, Florida, and Texas also find economies of scale in implementing on-farm sanitation practices (Paggi, Yamazaki, Ribera, Palma, and Knutson, 2013; Ribera et al., 2014).

#### 2. Materials and methods

#### 2.1. Survey design and implementation

We conduct an original national survey of fruit and vegetable growers to analyze the prevalence of food safety measures required by the Produce Rule. The survey includes questions on usage of food safety practices specifically stipulated in the Produce Rule--microbial testing, field monitoring, preventive actions, written documentation, and treatment of soil amendments-along with background information on farm economics, farm characteristics, and use of marketing channels. For microbial testing, we asked growers whether the farm collected water, soil amendment, and/or crop samples for testing. For field monitoring, we asked whether the fields were monitored for flooding, animal intrusion, and/or other contamination. For preventive food safety, we asked growers whether harvest containers were sanitized prior to harvest or if new containers were used, whether produce was washed prior to sale, whether the farm had contractual food safety obligations or employed third party food safety audits, and whether measures were taken to ensure employee sanitation and hygiene (e.g., training, tool sanitation, toilet and hand washing facilities, etc.). For written documentation, we asked respondents whether the farm kept written records for various food safety practices. Lastly, for treatment of soil amendments, we asked growers whether animalbased soil amendments were used and, if so, whether or not they were treated.

The survey was administered electronically using Qualtrics software. We collected data in person at eight major produce grower conferences across the U.S. and via the Internet through online grower listservs provided by several state fruit and vegetable growers' associations, university Extension services, and other grower organizations.<sup>3</sup> A booth was set up at each conference alongside other exhibitors in the trade show. As growers passed by

<sup>&</sup>lt;sup>2</sup> On September 13, 2017, the FDA proposed a rule to extend the dates for compliance with the agricultural water provisions by an additional two years beyond the dates currently established in the rule (See 82 FR 42963: https://www.federalregister.gov/d/2017-19434).

<sup>&</sup>lt;sup>3</sup> Appendix A includes detailed lists of grower conferences and online Listservs from which responses were collected.

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